

# **Safety Reports**

## **OTC NSAID: Ibuprophen**

### **Introductory Statement**

The source of these reports are primarily from the FDA's Adverse Event Reporting System (AERS) and/or the published medical literature. AERS is a spontaneous, voluntary surveillance system. Reports are voluntarily reported by health care professionals and consumers to either the FDA directly or to the manufacturer. The manufacturer is required to submit these reports to the Agency for products with an NDA.

### **GI bleeding related to Ibuprophen**

All Case Reports Submitted on GI Bleeding reported in association with OTC NSAID – ibuprofen (105) reported for January 1998-December 2001.



02-JAN-1998-0072



McNEIL CONSUMER PF  
FORT WASHINGTON

Individual Safety Report



\*3013882-5-00\*

**McNEIL**  
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_\_\_ of \_\_\_\_\_

<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient Identifier [Redacted]	2. Age at time of event: or _____ 2 yrs Date of birth: [Redacted]	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Children's Motrin Ibuprofen Oral Suspension #2		2. Dose, frequency & route used #1 100 mg, bid-tid prn, po #2	
In confidence				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 7/6/97-7/17/97; 12 days #2		4. Diagnosis for use (indication) #1 fever #2	
<b>B. Adverse event or product problem</b>				5. Event abated after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 ( ) Yes ( ) No ( ) N/A		6. Lot # (if known) #1 Unknown #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				7. Exp. date (if known) #1 Unknown #2		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage (X) other: recovered				9. NDC # - for product problems only (if known) -		10. Concomitant medical products and therapy dates (exclude treatment of event) amoxicillin, BENADRYL® Sect B5 cont; to Motrin use. On 8/11/97, pt seen by surgeon for follow-up. Surgeon's note to primary MD: Pt afebrile, abd soft without masses, healthy 2 yo.	
3. Date of event (mo/day/yr) 7/17/97		4. Date of this report (mo/day/yr) 12/18/97		<b>G. All manufacturers</b>			
5. Describe event or problem Physician's report of DUODENAL ULCER PERFORATION allegedly associated w/use of Children's Motrin Ibuprofen Oral Suspension in 2 yo. According to MD, pt diagnosed w/ear infection & fever on 7/6/97. Amox prescribed. Pt's fever treated w/Motrin prn. On 7/10/97, pt presented w/generalized RASH x1 D, loose stools (DIARRHEA), & fever. MD diagnosed "fever rash" & prescribed BENADRYL®. On 7/11/97, pt returned w/worsening rash, & swelling of face, feet, hands, & around eyes (EDEMA). Ears red & full of fluid. Amox, Motrin & BENADRYL cont'd. On 7/17/97, pt returned w/persistent fever/irritability (NERVOUSNESS), diarrhea x2 D, & VOMITING x10 on 7/14/97; rash resolved. On exam, pt "tender w/walking", abd distended/tender, & decreased bowel sounds. Pt sent to hosp for abd X-ray, hydrated, & transferred to 2nd hosp for surg/radiology consults. On 7/18/97, exploratory surg performed. Surgeon's report: duodenal ulcer w/perforation & multiple secondary abscesses. Pt dc'd on 7/30/97. Final Dx: perforated duodenal ulcer w/abscesses possibly related (see Sect C10)				1. Contact office name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-233-7820	
6. Relevant tests/laboratory data, including dates 7/10/97: temp measured in doctor's office 98.9 degrees Fahrenheit; 7/11/97: temp measured in doctor's office 99.9 degrees Fahrenheit; 7/13/97-7/15/97: temp measured by parents ranged from 101.2 to 103 degrees Fahrenheit; (see Sect B7)				4. Date received by manufacturer (mo/day/yr) 12/09/97		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) reports previous use of Children's Motrin Suspension without problems; diagnosed prior to event with ear infection; NKDA  Sec B6 cont'd: 7/17/97: Abdominal X-ray-free air noted				5. (A) NDA # 20-516 IND # PLA # pre-1938 ( ) Yes  OTC product (X) Yes		6. Adverse event term(s) RASH EDEMA DIARRHEA VOMITING ULCER DUODEN PE NERVOUSNESS	
8. Mfr. report number 0905793A				<b>E. Initial reporter</b>			
9. Health professional? (X) Yes ( ) No				1. Name, address & phone # [Redacted] MD [Redacted] Drive [Redacted]		3. Occupation physician	
10. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk							



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



28-JAN-1998-0031

**OLUNTARY**  
th professionals o  
ts and product pr

Individual Safety Report



\*3022422-6-00\*

Page 1 of 1

**A. Patient information**

1. Patient identifier <u>2595120</u>	2. Age at time of event: <u>78</u> or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or <u>68</u> kgs
---	---	---	--

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo:day:yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo:day:yr) 8-21-97

4. Date of this report (mo:day:yr) 11-6-97

5. Describe event or problem

GI bleed

6. Relevant tests/laboratory data, including dates

hgb 5.1  
hct 15.5

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

past drinker

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) <small>from to or best estimate</small>	
#1 <u>Aspirin</u>		#1	
#2 <u>Aspirin</u>		#2	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 <u>325mg Tpo QD</u>		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <u>200mg 4-5/day</u>		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 <u>pain</u>		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <u>pain</u>		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	10. Concomitant medical products and therapy dates (exclude treatment of event)	
#1	#1	<u>Pancrease</u>	
#2	#2		
9. NDC # (for product problems only)			

**D. Suspect medical device**

1. Brand name		4. Operator of device	
		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
2. Type of device		5. Expiration date (mo:day:yr)	
3. Manufacturer name & address		7. If implanted, give date (mo:day:yr)	
6. model #		8. If explanted, give date (mo:day:yr)	
catalog #			
serial #			
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo:day:yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #			
<u>PHARM.D.</u> <u>DR.</u>			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation <u>Pharmacist</u>	4. Also reported to
			<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

RECEIVED AT DRUG SAFETY SURVEILLANCE



28-JAN-1998-0032

Individual Safety Report



\*3022422-6-00\*

HOSP PHARMACY HSP  
DR. S



1998 JAN 28  
10:00 AM  
NEW YORK, NY

20/2  
CDER

#MLU11





17-FEB-1998-0071

For use by user-fac  
distributors and manufa  
MANDATORY



\*3029915-6-00\*

**A. Patient information**

1 Patient identifier: [redacted] 2 Age at time of event: -NI or Date of birth: -NI 3 Sex:  female  male 4 Weight: -NI lbs or -NI kgs

**B. Adverse event or product problem**

1  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply):  
 death 08/03/95  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other

3 Date of event: unknown 4 Date of this report: 02/10/98

5 Describe event or problem  
 According to a report received from the law firm of [redacted] an adult male was hospitalized with "gastro-intestinal bleeding secondary to multiple gastric ulcers which resulted in hepatic encephalopathy." "ultimately resulting in his death." The patient sustained an unspecified injury on July 14, 1994 and it is believed that he began taking Nuprin and/or Advil. The frequency, dose and length of therapy are all unknown. The patient died on August 3, 1995. No other information is available.

6 Relevant tests/laboratory data including dates:  
 No information provided.

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
 Medical history unknown.  
 Allergy history unknown.

**C. Suspect medication(s)**

1 Name (give labeled strength & mfr/labeler, if known)  
 #1 Advil (R) (Ibuprofen) Tablets  
 #2 Nuprin

2 Dose, frequency & route used  
 #1 unknown  
 #2 unknown

3 Therapy dates (if unknown, give duration)  
 #1 Duration unk.  
 #2 Duration unk.

4 Diagnosis for use (indication)  
 #1 injury-NOS  
 #2 injury-NOS

5 Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6 Lot # (if known) 7 Exp. date (if known)  
 #1 Unknown #1 -NA  
 #2 Unknown #2 -NA

8 Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9 NDC # - for product problems only (if known)  
 0573 - 0150

10 Concomitant medical products and therapy dates (exclude treatment of event)  
 None reported.

**D. Suspect medical device**

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device  
 health professional  
 lay user/patient  
 other

5 Expiration date

6 model #  
 catalog #  
 serial #  
 lot #  
 other #

7 If implanted, give date

8 If explanted, give date

9 Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on

10 Concomitant medical products and therapy dates (exclude treatment of event)

**E. Initial reporter**

1 Name, address & phone #  
 [redacted]  
 P.O. Box [redacted] United States

2 Health professional?  yes  no

3 Occupation -NA

4 Initial reporter also sent report to FDA  
 yes  no  unk



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Handwritten notes: 2/10/98, 2/10/98

RECEIVED AT DRUG SAFETY SURVEILLANCE  
 17-FEB-1998-1701

Mc  
 Exp -  
 (continued)

report does not  
 at medical per:  
 or, manufacturer  
 contributed to th  
 je \_\_\_ of \_\_\_

Individual Safety Report  
 \*3029915-6-00\*

Refer to guidelines for specific instructions

**F. For use by user facility/distributor—devices only**

1. Check one  
 user facility  distributor

2. UF/Dist report number

3. User facility or distributor name/address

4. Contact person

5. Phone Number

6. Date user facility or distributor became aware of event (mo/day/yr)

7. Type of report  
 initial  
 follow-up # \_\_\_\_\_

8. Date of this report (mo/day/yr)

9. Approximate age of device

10. Event problem codes (refer to coding manual)  
 patient code \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 device code \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

11. Report sent to FDA?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

12. Location where event occurred  
 hospital  outpatient diagnostic facility  
 home  ambulatory surgical facility  
 nursing home  outpatient treatment facility  
 other \_\_\_\_\_ specify \_\_\_\_\_

13. Report sent to manufacturer?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

14. Manufacturer name/address

**H. Device manufacturers only**

1. Type of reportable event  
 death  
 serious injury  
 malfunction (see guidelines)  
 other: \_\_\_\_\_

2. If follow-up, what type?  
 correction  
 additional information  
 response to FDA request  
 device evaluation

3. Device evaluated by mfr?  
 not returned to mfr  
 yes  evaluation summary attached  
 no (attach page to explain why not) or provide code \_\_\_\_\_

4. Device manufacture date (mo/yr)

5. Labeled for single use?  
 yes  no

6. Evaluation codes (refer to coding manual)  
 method \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 results \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 conclusions \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

7. If remedial action initiated, check type  
 recall  notification  
 repair  inspection  
 replace  patient monitoring  
 relabeling  modification/adjustment  
 other: \_\_\_\_\_

8. Usage of device  
 initial use of device  
 reuse  
 unknown

9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number

**G. All manufacturers**

1. Contact office - name/address (& mfgng site for devices)  
 Whitehall-Robins  
 Medical Department  
 5 Giralda Farms  
 Madison, NJ 07940-0871

2. Phone number  
 201-660-5500

3. Report source (check all that apply):  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other

4. Date received by manufacturer (mo/day/yr)  
 02/03/98

5. (A) NDA # 18-989  
 IND # -NA-  
 PLA #  
 pre-1938  yes  
 OTC product  yes

6. If IND, protocol #

7. Type of report (check all that apply):  
 5-day  15-day  
 10-day  periodic  
 Initial  follow-up # \_\_\_\_\_

8. Adverse event term(s)  
 HEM GI  
 ULCER STOMACH  
 ENCEPHALOPATHY

9. Mfr. report number  
 98-0150-011

10.  Additional manufacturer narrative and/or 11.  Corrected data

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to

Reports Clearance Office, PHS  
 Hubert H. Humphrey Building, Room 721-B  
 200 Independence Avenue, S.W.  
 Washington, DC 20201  
 ATTN: PRA

and to  
 Office of Management and Budget  
 Paperwork Reduction Project (0910-0291)  
 Washington, DC 20503

Please do NOT return this form to either of these addresses.



10-MAR-1998-0004

Voluntary reporting

Health professionals and

Individual Safety Report

\*3049002-0-00\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Best Copy

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
--	--	--	-------------------------------

B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

*Handwritten description of adverse event, including symptoms and duration.*

6. Relevant tests/laboratory data, including dates

*Handwritten laboratory test results and dates.*

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

*Handwritten medical history notes.*

#1 \_\_\_\_\_

#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) from to (or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

*Handwritten concomitant medical products.*

D. Suspect medical device

1. Brand name \_\_\_\_\_

2. Type of device \_\_\_\_\_

3. Manufacturer name & address

*Handwritten manufacturer name and address.*

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

*Handwritten name and address: AMARILLO BLVD, AMARILLO, TX 79130*

2. Health professional?  yes  no

3. Occupation \_\_\_\_\_

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178



10-MAR-1998-0015

VOLUNTA...  
alth professio  
nts and produ

Individual Safety Report



\*3049043-3-00\*

Page 1

**A. Patient information**

1. Patient identifier 7149 <small>(in confidence)</small>	2. Age at time of event: 58 or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or 68.8 kgs
---	---	--	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 4/18/96	4. Date of this report (mo/day/yr) 12/24/96
---	--

5. Describe event or problem

Pt cc: weakness: presynopal episodes began vomiting blood in stool. Pt taking ibuprofen OTC. No NSAID on same profile. EGD showed esophageal ulcer & varices & a gastric ulcer & duodenitis. Tx omeprazole.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Hepatitis cirrhosis  
Alcoholism

1. Name (give labeled strength & manufacturer, if known)

#1 Ibuprofen OTC

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from to (or best estimate))
#1 OTC (???)	#1 ? - 4/18/96
#2	#2

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 ? unknown	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

9. NDC # (for product problems only)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
5. Expiration date (mo/day/yr)	6. model #
7. If implanted, give date (mo/day/yr)	catalog #
8. If explanted, give date (mo/day/yr)	serial #
	lot #
	other #
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name (print name)  
[Redacted] M.D.  
6011 Armarillo Blvd West  
Arlark 1100, TX 74106  
(800) 365-9703 ext: 70-1

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation RPH	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>		



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178



MEDWAT

10-MAR-1998-0038

Individual Safety Report



\*3049080-9-00\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

Page 1 of 1

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight  
AGE: 63 yrs | MALE | 92.1 kg

C. Suspect Medication(s)

1. Name  
#1: IBUPROFEN

B. Adverse Event or Product Problem

1.  Adverse Event [ ] Product problem  
2. Outcomes attributed to adverse event  
 death [ ] disability  
 life-threatening [ ] congenital anomaly  
 Hospitalization [X] required intervention to  
initial or prolonged prevent impairment/damage  
[ ] other

2. Dose, frequency & route used | 3. Therapy dates  
#1: 400MG, BID, PO OR | #1: 04/06/97-04/09/97

4. Diagnosis for use (indication) | 5. Event abated after use  
#1: HEADACHE \*\*\* OTC \*\*\* | #1: [YES]

3. Date of event | 4. Date of this report  
04/09/97 | 05/13/97

5. Describe event or problem  
ANEMIA, DIZZINESS, HYPOTENSION, UGI BLEED

EGD ⊕  
+x lansoprazole.

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after  
#1: | #1: | #1: [ ]  
reintroduction

9. (Not applicable to adverse drug event reports)

6. Relevant test/laboratory data, including dates  
PLEASE SEE ATTACHED

REC'D.

MAR 10 1998

MEDWATCH CTU

10. Concomitant medical products/therapy dates (exclude treatment)

7. Other relevant history, including preexisting medical conditions

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [REDACTED] : PHARM

Mail to: MedWatch  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

2. Health professional? | 3. Occupation | 4. Reported to Mfr.  
[YES] | PHARMACIST | [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

OTC  
78809

RECEIVED AT DRUG SAFETY SURVEILLANCE



10-MAR-1998-0039

Individual Safety Report  
\*3049080-9-00\*

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICA..

Section B. Part 6. Relevant Test/Laboratory Data Continued:

TEST: PYLORI RESULTS: <15 EIA UNITS H:15/L: COLLECTION DATE: 4/9/97@19:12

TEST: oHGB RESULTS: L 9.5 gm/dL H:18/L:12 COLLECTION DATE: 4/9/97@19:12

TEST: HCT RESULTS: L 27.9 % H:52/L:37 COLLECTION DATE: 4/9/97@19:12

REC'D.

MAR 10 1998

MEDWATCH CTU

CDER  
# 78807  
2092



19-MAR-1998-0798

VOLUNTARY  
Health professionals of  
its and product pro

Individual Safety Report



\*3057641-6-00\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDEK

Page 1 of 2

**A. Patient information**

1. Patient identifier <b>737</b> In confidence	2. Age at time of event: or <b>EE</b> Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or <b>95</b> kgs
--	--	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) **6/29/97**

4. Date of this report (mo/day/yr) **3/10/98**

5. Describe event or problem  
*See attached*

**REC'D.**  
MAR 17 1998  
MEDWATCH CTU

6. Relevant tests/laboratory data, including dates  
*See attached*

**REC'D.**  
MAR 19 1998  
MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
*See attached*

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 <b>ibuprofen</b>	2. Dose, frequency & route used #1 <b>200mg(?) 2-3 qpm po qd-2 months</b>	3. Therapy dates (if unknown, give duration) from to (or best estimate): #1 <b>1-2 months</b>
#2	#2	#2

4. Diagnosis for use (indication)

#1 <b>arthritic pain</b>	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

6. Lot # (if known)

#1 <input checked="" type="checkbox"/>	7. Exp. date (if known)
#2	#2

8. Event reappeared after reintroduction

#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

9. NDC # (for product problems only)  
**-**

10. Concomitant medical products and therapy dates (exclude treatment of event)  
**Septin DS x 4 days  
Diabinese  
Lanolin**

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address  
*279667*

4. Operator of device  
 health professional  
 lay user/patient  
 other:

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see c)**

1. Name, address & phone #  
**[Redacted], Pharm. D.  
Medical Center Pharmacy  
Road**

2. Health professional?  
 yes  no

3. Occupation  
**Pharmaceut**

4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
or FAX to:  
1-800-FDA-0178

RECEIVED AT DRUG SAFETY SURVEILLANCE



19-MAR-1998-0799

Individual Safety Report



\*3057641-6-00\*

IDENTIFIER: 88yo female; 6/29/97  
DIAGNOSIS/PROCEDURE: Patient presented in the ED passing blood in the rectum with history of a gastric antral ulcer (1993), insulin-dependent diabetes, chronic atrial fibrillation, and recent respiratory tract and urinary tract infections.  
ALLERGIES: none  
SUSPECTED MED(S): ibuprofen  
SIGNS & SYMPTOMS: In the ED, the patient's Hgb = 6.3 (12-16 gm/dl). This was compared to a Hgb = 10.3 on June 26, 1997. Following insertion and removal of a nasogastric tube there was no evidence of an active upper GI bleed. The patient denied abdominal pain although she was admitted complaining of pain in her ribs. She had been using Motrin<sup>®</sup>, 2 to 3 pills in the evening, for 1 to 2 months for arthritis pain.  
ACTION TAKEN: Supportive therapy was limited because this patient is a Jehovah's Witness. Vitamin K, iron, vitamin B<sub>12</sub>, Epogen<sup>®</sup>, and H<sub>2</sub> Antagonist therapy were instituted. During hospitalization the Hgb ranged from 5 to 5.3 and Hct ranged from 13 to 15.7 (37-47%).  
OUTCOME: Following eight days of hospitalization the patient was discharged in satisfactory condition.

*CDER  
#79363  
20/92*

REC'D.

MAR 19 1998

MEDWATCH OTU



31-MAR-1998-0905

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTAR  
by health professionals  
events and product

Individual Safety Report



\*3061855-9-00\*

Page 1 of 1 VER

### A. Patient information

1. Patient identifier <u>163393</u> <small>In confidence</small>	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
--	--	--	---

### B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year) 05-1996

4. Date of this report (month/year) 03-1998

5. Describe event or problem

GI bleed

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

### C. Suspect medication(s)

1. Name (give labeled strength & ml/labeler, if known)

#1 Advil

#2 ASA

2. Dose, frequency & route used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (month/year or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

### D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

**REC'D.**

**MAR 3 1 1998**

**MEDWATCH CTU**

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (month/year)

6. model # \_\_\_\_\_

7. If implanted, give date (month/year)

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

80153

### E. Reporter (see confidentiality section on back)

1. Name, address & phone

\_\_\_\_\_, Ph.D., FASCP  
\_\_\_\_\_  
P.O. Box \_\_\_\_\_  
\_\_\_\_\_, Phone: \_\_\_\_\_

2. Health professional?  yes  no

3. Occupation Pharmacist

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

RECEIVED AT DRUG SAFETY SURVEILLANCE



28-APR-1998-1491

\*3072074-4-00\*

NTA... reporting  
of adverse  
product problems

*ced*

FDA Use Only (AHFS)

See OMB statement on reverse

Trace unit sequence #	81975
-----------------------	-------

Page \_\_\_ of \_\_\_

**A. Patient information**

1. Patient identifier <i>136252</i> In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	--	--	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/mafunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) *03-1998*

4. Date of this report (mo/day/yr) *03-1998*

5. Describe event or problem

*U GI Bleed*

REC'D.  
APR 28 1998  
MEDWATCH CTU

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 *Advil*

#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (mo/yr) (or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

*\_\_\_\_\_, Ph.D., FASCP*

*\_\_\_\_\_, Hospital*

*P.O. Box \_\_\_\_\_*

*\_\_\_\_\_, Phone: \_\_\_\_\_*

2. Health professional?  yes  no

3. Occupation *pharmacist*

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178



\*3072154-3-00\*

RECEIVED AT DRUG SAFETY SURVEILLANCE



28-APR-1998-1512

or VOLUNTARY reporting  
health professionals of adverse  
events and product problems

CDEM

FDA Use Only (AHFS)

Trace and  
sequence #

81959

Form Approved: OMB No. 0916-0291 Expires: 12/31/94  
See OMB statement on reverse

Page \_\_\_ of \_\_\_

**A. Patient information**

1. Patient identifier <i>030962</i>	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ___ lbs or ___ kgs
--	--	--	---------------------------------------

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyyy) *07-1998*

4. Date of this report (m/d/yyyy) *03-1998*

5. Describe event or problem  
*Upper GI Bleed*

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 *Advil, ASA, Alcohol*

#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (month to or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (m/d/yyyy)

6. model # \_\_\_\_\_

catalog # \_\_\_\_\_

serial # \_\_\_\_\_

lot # \_\_\_\_\_

other # \_\_\_\_\_

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

*Ph.D., FASCP*  
*Hospital*  
*P.O. Box*  
*Phone*

2. Health professional?  yes  no

3. Occupation *pharmacist*

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

REC'D.  
APR 28 1998  
MEDWATCH CTU



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



21-APR-1998-2257

age \_\_\_ of \_\_\_



\*3072286-X-00\*

**A. Patient information**

1. Patient identifier: 8110  
In confidence

2. Age at time of event: 80  
or Date of birth: \_\_\_\_\_

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death (m/d/yyr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (m/d/yyr): 10/9/97

4. Date of this report (m/d/yyr): 11/18/97

5. Describe event or problem:  
BRB per rectum. Lower GI B  
dehydration 2° blood loss  
USA IDs DC'd.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
 #1 Aspirin CN 103  
 #2 Aspirin M5102

2. Dose, frequency & route used:  
 #1 a couple a day  
 #2 6 tabs daily

3. Therapy dates (if unknown, give duration from/to (or best estimate)):  
 #1 → 10/9/97  
 #2 → 11/9/97

4. Diagnosis for use (indication):  
 #1 osteoarthritis  
 #2 !

5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

7. Exp. date (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

8. Event reappeared after reintroduction:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only): \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event): \_\_\_\_\_

**D. Suspect medical device**

1. Brand name: \_\_\_\_\_

2. Type of device: \_\_\_\_\_

3. Manufacturer name: MEDWATCH

4. Operator of device:  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (m/d/yyr): \_\_\_\_\_

7. If implanted, give date (m/d/yyr): \_\_\_\_\_

8. If explanted, give date (m/d/yyr): \_\_\_\_\_

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyr)

10. Concomitant medical products and therapy dates (exclude treatment of event): \_\_\_\_\_

Ref	Range	HGB	HCT
Yr:1997	SPEC	14-18 g/dL	42-52 %
11/04/97	15:43 BLO	10.3 L	32.4 L
10/15/97	10:49 BLO	10.0 L	30.8 L
10/14/97	14:21 BLO	10.4 L	30.6 L
10/13/97	11:00 BLO	10.4 L	31.9 L
10/13/97	05:00 BLO	9.7 L	29.8 L
10/12/97	17:45 BLO	10.6 L	32.7 L
10/12/97	10:28 BLO	10.2 L	30.3 L
10/11/97	11:45 BLO	11.2 L	34.0 L
10/10/97	18:00 BLO	11.5 L	36.1 L
10/10/97	11:45 BLO	11.3 L	33.8 L
10/10/97	05:00 BLO	10.6 L	33.3 L
10/10/97	02:30 BLO	9.2 L	28.4 L
10/09/97	17:27 BLO	10.7 L	32.6 L
10/09/97	15:32 BLO	9.7 L	29.6 L
10/09/97	08:34 BLO	11.1 L	35.4 L
10/09/97	06:26 BLO	12.5 L	39.0 L

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
Osteoarthritis  
HTN  
Ethanol use

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #:  
STVHCS (119)  
7400 Merton Minter Blvd.  
San Antonio, Texas 78284

2. Health professional?  yes  no

3. Occupation: Shawn D.

4. Also reported to:  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
 5600 Fishers Lane  
 Rockville, MD 20852-9787

or FAX to:  
 1-800-FDA-0178



11-MAY-1998-0802

LUNRARY rep  
professionals of a  
and product probl  
CDER



\*3074521-0-00\*

82973

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

**A. Patient information**

1. Patient identifier 04082811 In confidence	2. Age at time of event: 85 or _____ Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or 56.3 kgs
--	---	---	--------------------------------------

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 12-11-97

4. Date of this report (mo/day/yr) 2-7-98

5. Describe event or problem  
  
GI bleed

6. Relevant tests/laboratory data, including dates  
  
hgb 8.5  
hct 25.9

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
#1 Advil 200mg  
#2 \_\_\_\_\_

2. Dose, frequency & route used  
#1 po 2-3/day  
#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration)  
#1 \_\_\_\_\_  
#2 \_\_\_\_\_

4. Diagnosis for use (indication)  
#1 allergies  
#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

6. Lot # (if known)  
#1 \_\_\_\_\_  
#2 \_\_\_\_\_

7. Exp. date (if known)  
#1 \_\_\_\_\_  
#2 \_\_\_\_\_

8. Event reappeared after reintroduction  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

9. NDC # (for product problems only)  
#1 \_\_\_\_\_  
#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)  
Insulin  
Ser-Ap-Ea

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_  
catalog # \_\_\_\_\_  
serial # \_\_\_\_\_  
lot # \_\_\_\_\_  
other # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #  
\_\_\_\_\_  
PHARM. D.  
\_\_\_\_\_  
DR.  
\_\_\_\_\_

2. Health professional?  
 yes  no

3. Occupation  
Pharmacist

4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178



23-JUL-1998-0068

\*3108687-0-00\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

FDA Use Only

**A. Patient information**

1 Patient identifier [redacted]	2 Age at time of event: 56 or Date of birth: [redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight -NI lbs -NI kgs
------------------------------------	---	--	--------------------------------

**B. Adverse event or product problem**

1  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other

3 Date of event unknown	4 Date of this report 07/16/98
----------------------------	-----------------------------------

5 Describe event or problem

In association with the use of Advil, the reporter wrote that following use of product for 4 years she was hospitalized for 5 days (admission date unknown). The reporter additionally wrote that she received "6 pints of blood in 2 days." According to discharge papers dated 6/11/98, she was diagnosed with diffuse gastritis, gastric ulcer, hiatal hernia, anemia (secondary to bleeding), colonic polyps, and bronchitis. She was discharged on the following medications: Pepcid (famotidine) 20mg, Tylenol (acetaminophen 650mg, Zithromax (azithromycin) 250mg, Reglan (metoclopramide) 10mg, ferrous sulfate 325mg, Allegra (fexofenadine) 60mg, and Benadryl (diphenhydramine) 25mg. No additional information is known at this time. Several attempts to reach the reporter by telephone were unsuccessful. Pending additional information. No further symptoms or sequelae were reported.

6 Relevant tests/laboratory data, including dates

CBC with differential performed in hospital (results unknown).

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Medical history unknown.

Allergic to penicillin.

**C. Suspect medication(s)**

1 Name (give labeled strength & mfr labeler, if known)

#1 Advil (R) (Ibuprofen) Tablets

#2 -NA

2 Dose, frequency & route used as directed

#1 -NA

3 Therapy dates (if unknown, give duration, from to or best year(s))

#1 -NA

#2 -NA

4 Diagnosis for use (indication)

#1 pain, inflammation of ankles and knees

#2 -NA

5 Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6 Lot # (if known)

#1 Unknown

#2 -NA

7 Exp. date (if known)

#1 -NA

#2 -NA

8 Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9 NDC # - for product problems only (if known)

0573 - 0150

10 Concomitant medical products and therapy dates (exclude treatment of event)

None reported.

**D. Suspect medical device**

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device

health professional  
 lay user/patient  
 other

5 Expiration date

6 Model #

7 If implanted, give date

8 If explanted, give date

9 Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on

10 Concomitant medical products and therapy dates (exclude treatment of event)

**E. Initial reporter**

1 Name, address & phone #

[redacted] St. United States

JUL 24 1998

2 Health professional?  
 yes  no

3 Occupation  
-NA

4 Initial reporter also sent report to FDA  
 yes  no  unknown



Submission of a report does not constitute an admission that medical personnel, user, facility, distributor, manufacturer or product caused or contributed to the event.

7/16/98

RECEIVED AT DRUG SAFETY SURVEILLANCE



23-JUL-1998-0069

Individual Safety Report



\*3108687-0-00\*

Telephone (973) 660-5500

Website address: <http://healthfront.com>



July 22, 1998

NDA 18-989

Advil<sup>®</sup> Tablets, Caplets, Gel Caplets  
(Ibuprofen 200 mg)

15-Day Adverse Experience Report

Center for Drug Evaluation and Research  
Food and Drug Administration  
Attention: Central Document Room  
12229 Wilkins Avenue  
Rockville, MD 20852



Dear Sir/Madam:

Please refer to NDA 18-989 for Advil<sup>®</sup> Tablets, Caplets, Gel Caplets (ibuprofen 200 mg) sponsored by Whitehall-Robins Healthcare ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to 21CFR 314.80(c)(1)(i), Whitehall-Robins herewith submits an adverse experience report meeting the criteria for 15-day reporting (i.e., serious and unlabeled). Manufacturer Control # 98-0100-077 describes the use of ibuprofen (manufacturer unknown) in a fifty-six year old female.

If you have any questions regarding this information, please contact the undersigned at (973) 660-5753 or Ms. Mary Davis at (973) 660-5825.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

*Mary A. Davis*  
Sharon Heddish *for*  
Vice President  
Worldwide Regulatory Affairs

JUL 24 1998

### F. For use by user facility/distributor—devices only

1 Check one  
 user facility  distributor

2 UF/Dist report number

3 User facility or distributor name/address

4 Contact person

5 Phone Number

6 Date user facility or distributor became aware of event (mo/day/yr)

7 Type of report  
 initial  
 follow-up # \_\_\_\_\_

8 Date of this report (mo/day/yr)

9 Approximate age of device

10 Event problem codes (refer to coding manual)  
 patient code \_\_\_\_\_  
 device code \_\_\_\_\_

11 Report sent to FDA?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

12 Location where event occurred  
 hospital  outpatient diagnostic facility  
 home  ambulatory surgical facility  
 nursing home  outpatient treatment facility  
 other \_\_\_\_\_

13 Report sent to manufacturer?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

14 Manufacturer name/address

### H. Device manufacturers only

1 Type of reportable event  
 death  
 serious injury  
 malfunction (see guidelines)  
 other \_\_\_\_\_

2 If follow-up, what type?  
 correction  
 additional information  
 response to FDA request  
 device evaluation

3 Device evaluated by mfr?  
 not returned to mfr  
 yes  evaluation summary attached  
 no (attach page to explain why not) or provide code \_\_\_\_\_

4 Device manufacture date (mo/yr)

5 Labeled for single use?  
 yes  no

6 Evaluation codes (refer to coding manual)  
 method \_\_\_\_\_  
 results \_\_\_\_\_  
 conclusions \_\_\_\_\_

7 If remedial action initiated, check type  
 recall  notification  
 repair  inspection  
 replace  patient monitoring  
 relabeling  modification adjustment  
 other \_\_\_\_\_

8 Usage of device  
 initial use of device  
 reuse  
 unknown

9 If action reported to FDA under 21 USC 360(f), list correction removal reporting number

### G. All manufacturers

1 Contact office - name/address (if mailing site for devices)

2 Phone number  
 973-660-5500

3 Report source (check all that apply)  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other \_\_\_\_\_

4 Date received by manufacturer (mo/day/yr)  
 07/06/98

5 If IND, protocol #

6 Type of report (check all that apply)  
 5-day  15-day  
 30-day  90-day  
 initial  follow-up # \_\_\_\_\_

7 Mfr. report number  
 98-0150-077

8 Adverse event term(s)  
 GASTRITIS  
 ULCER STOMACH  
 HERNIA  
 ANEMIA  
 NEOPL  
 BRONCHITIS

10  Additional manufacturer narrative and/or  Corrected data

**JUL 24 1998**

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

INDIVIDUAL SAFETY REPORT  
 F distrib M/ #3120688-5-00-01\*

910-0291 Expires 12/31/94  
 OMB statement on reverse  
 ( 98-2180 )

Page 1 of 1

FDA Use Only

**A. Patient information**

1 Patient identifier: [redacted]  
 2 Age at time of event: 55  
 or \_\_\_\_\_  
 Date of birth: -NI

3 Sex:  female  male

4 Weight: 170 lbs  
 -NI kgs

In confidence

**B. Adverse event or product problem**

1  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply):  
 death (mo/day/yr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3 Date of event (mo/day/yr): 6/7/98  
 4 Date of this report (mo/day/yr): 08/10/98

5 Describe event or problem

This is a follow up to a report received of a 56 year-old woman who reportedly developed gastric ulcers, diffuse gastritis, hiatal hernia, colonic polyps, anemia (secondary to ulcer bleeding) and bronchitis. According to medical records received on 8/6/98, the woman was admitted on 6/5/98 complaining of weakness, dizziness, shortness of breath and a clear productive cough. Past records indicate that she was admitted on 8/13/96 for pain of knees, calves and at that time was taking 3-4 Advil tablets daily. At that time she was released on Naprosyn 500mg BID and Zostrix HP topical ointment. Medical records dated 6/24/98 indicate that she was admitted for upper GI bleeding and was given 6 units of packed red blood cells. Surgical pathology report showed chronic superficial gastritis, gastric ulcer and features suggestive of hyperplastic polyps of the sigmoid colon. Special stains for H. Pylori microorganisms on gastric ulcer biopsy specimen were negative for H. Pylori. The patient had not seen nausea, vomiting or blood in stools. She was given Prevacid (lansoprazole) 15mg BID and Metamucil. Records of 7/22/98 indicate that the patient was still

6 Relevant tests/laboratory data, including dates

Gastric ulcer biopsy specimen were negative for H. Pylori. Otherwise ECG normal.  
 As of 7/17/98: Hgb 12.5g/dL; Hct 38.9%; MCV 85.3fL; MCH 27.4 pg; MCHC 32.1%.

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic renal dysfunction, etc.)

Allergic to penicillin.

**C. Suspect medication(s)**

1 Name (give labeled strength & mfr/labeler, if known)  
 #1 Advil (R) (Ibuprofen) Tablets  
 #2 Naprosyn (naproxen)

2 Dose, frequency & route used  
 #1 2 tabs q4-8hrs  
 #2 500 mg BID

3 Therapy dates (if unknown, give duration)  
 #1 3.5 year(s)  
 #2 1 month(s)

4 Diagnosis for use (indication)  
 #1 pain and inflammation of right knee  
 #2 pain of right knee

5 Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6 Lot # (if known)  
 #1 8LG462  
 #2 -NA

7 Exp. date (if known)  
 #1 2 / 00  
 #2 -NA

8 Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9 NDC # - for product problems only (if known)  
 0573 - 0150 -

10 Concomitant medical products and therapy dates (exclude treatment of event)  
 None reported.

**D. Suspect medical device**

1 Brand name \_\_\_\_\_

2 Type of device \_\_\_\_\_

3 Manufacturer name & address \_\_\_\_\_

4 Operator of device  
 health professional  
 lay user patient  
 other \_\_\_\_\_

5 Expiration date (mo/day/yr) \_\_\_\_\_

6 model # \_\_\_\_\_

7 If implanted, give date (mo/day/yr) \_\_\_\_\_

8 If explanted, give date (mo/day/yr) \_\_\_\_\_

9 Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_

10 Concomitant medical products and therapy dates (exclude treatment of event)

**E. Initial reporter**

1 Name, address & phone #  
 Ms. [redacted]  
 [redacted] Street  
 United States  
 AUG 25 1998

2 Health professional?  yes  no

3 Occupation -NA

4 Initial reporter also sent report to FDA  yes  no  unk



Submission of a report does not constitute an admission that medical personnel, user, facility, distributor, manufacturer or product caused or contributed to the event.

Handwritten notes: MS/8/10/98, EE 8/10/98, 11/28/98

# Medication and Device Experience Report (continued)

Submission of a report is required for an admission that a facility, distributor, or manufacturer caused or contributed to the event.



U.S. SERVICES

Refer to guidelines for specific instructions

Page \_\_\_ of \_\_\_

FDA Use Only

### F. For use by user facility/distributor—devices only

1 Check one <input type="checkbox"/> user facility <input type="checkbox"/> distributor		2 UF/Dist report number	
3 User facility or distributor name/address			
4 Contact person		5. Phone Number	
6 Date user facility or distributor became aware of event (mo/day/yr)		7 Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	
8 Date of this report (mo/day/yr)		9	
10 Approximate age of device		10 Event problem codes (refer to coding manual) patient code: [ ] - [ ] - [ ] device code: [ ] - [ ] - [ ]	
11 Report sent to FDA? <input type="checkbox"/> yes (mo/day/yr) <input type="checkbox"/> no		12 Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> other _____	
13 Report sent to manufacturer? <input type="checkbox"/> yes (mo/day/yr) <input type="checkbox"/> no		14	
15 Manufacturer name/address			

### H. Device manufacturers only

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guidelines) <input type="checkbox"/> other _____		2 If follow-up, what type? <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation	
3 Device evaluated by mfr? <input type="checkbox"/> not returned to mfr <input type="checkbox"/> yes <input type="checkbox"/> evaluation summary attached <input type="checkbox"/> no (attach page to explain why not) or provide code _____		4 Device manufacture date (mo/yr)	
5 Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no		6 Evaluation codes (refer to coding manual) method: [ ] - [ ] - [ ] - [ ] results: [ ] - [ ] - [ ] - [ ] conclusions: [ ] - [ ] - [ ] - [ ]	
7 If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> patient monitoring <input type="checkbox"/> relabeling <input type="checkbox"/> modification/adjustment <input type="checkbox"/> other _____		8 Usage of device <input type="checkbox"/> initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown	
9 If action reported to FDA under 21 USC 360(f), list correction removal reporting number		10 <input type="checkbox"/> Additional manufacturer narrative and/or 11 <input type="checkbox"/> Corrected data	

### G. All manufacturers

1 Contact office - name/address (& mailing site for devices)  Whitehall-Robins Medical Department 5 Giralda Farms Madison, NJ 07940-0871		2 Phone number 973-660-5500	
3 Date received by manufacturer 08/06/98		3 Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other	
4 If IND, protocol #		5 (A)INDA # 18-989 IND # -NA PLA # pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes	
6 Type of report (check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1		8 Adverse event term(s)  GASTRITIS ULCER STOMACH HERNIA NEOPL ANEMIA	
7 Mfr. report number 98-0150-077			

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to...

Report Clearance Office, PHS  
Hubert H. Humphrey Building, Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20501  
ATTN: PRA

and to  
Office of Management and Budget  
Paperwork Reduction Project (0910-0291)  
Washington, DC 20503

Please do NOT return this form to either of these addresses.

ANG 2 1998

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting  
by health professionals of:  
events and product prob

Individual Safety Report

Form Approved OMB No. 0910-0291 Expires: 12/31/94



Page **CDER** of \_\_\_\_\_

### A. Patient information

1. Patient identifier	2. Age at time of event: <u>2</u> or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <u>23 1/2</u> lbs or <u>10.6</u> kgs
-----------------------	--	---	---

### B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/small functions)

2. Outcomes attributed to adverse event (check all that apply):  
 death  
 life-threatening  
 hospitalization -- initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (mo/day/yr): 6/19/98

4. Date of this report (mo/day/yr): 9-18-98

5. Describe event or problem

Massive hematemesis. Child had taken several doses of Ibuprofen for an upper respiratory tract illness and fever.

She required 2 blood transfusions.

6. Relevant tests/laboratory data, including dates

6/19/98 Admission hemoglobin 4.5, Hct 13.5  
 6/19/98 Emergency endoscopy in pediatric ICU revealed gastric bleed with overlying clot.  
 6/19 Spinal tap, CT scan of head, abdominal ultrasound, chest x-ray

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

Failure to thrive  
 Developmental delay

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) 100mg/5mL

#1 Children's Motrin, Ibuprofen oral suspension

#2 \_\_\_\_\_

2. Dose, frequency & route used  
 #1 1 teaspoon every 6 hrs  
as needed  
by mouth

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration; from to or best estimate)  
 #1 6/16/98 - 2 doses  
6/17/98 - 3 doses  
 #2 6/18/98 - 3 doses

4. Diagnosis for use (indication)  
 #1 Fever

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known)  
 #1 N/A

#2 \_\_\_\_\_

7. Exp. date (if known)  
 #1 N/A

#2 \_\_\_\_\_

8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)  
- Failure to thrive 4/97  
- Switched to Kindercal formula - gaining weight

### D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

### E. Reporter (see confidentiality section on back)

1. Name, address & phone #  
 [redacted], M.D., Professor and  
 Chairman of Pediatrics  
 [redacted] College, [redacted]

2. Health professional?  yes  no

3. Occupation  
M.D.

4. Also reported to  
 manufacturer  
 user/facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
 5600 Fishers Lane  
 Rockville, MD 20852-9787

or FAX to:  
 1-800-FDA-0178

CERT. #683 255 (IND)  
#683 258 (NDA)  
**MedWatch**

**Merck Human Health Division**

For use by user-facilities,  
distributors and manufacturer  
MANDATORY reporting

Merck Facility # (EP) 51-10000



The FDA Medical Products Reporting Program

Page 1

51

\*3141858-6-00-01\*

NO ATTACHMENT

<b>A. Patient Information</b>			
1. Patient Identifier [REDACTED] In confidence	2. Age at time of event: 69 years Date of Birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight Unk
<b>B. Adverse event or product problem</b>			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> life-threatening	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization-initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____			
3. Date of event (mo/day/yr) 09/20/98	4. Date of this report (mo/day/yr) 10/08/98		
5. Describe event or problem			
<p>A 5-year, double-blind, randomized, placebo-controlled extension study to examine the long-term safety and efficacy of oral alendronate in postmenopausal, osteoporotic women who previously received alendronate in conjunction with the fracture intervention trial.</p> <p>Information has been received concerning a 69 year old female with arthritis who entered a 5-year, double-blind, randomized, placebo-controlled extension study to examine the long-term safety and efficacy of oral alendronate in conjunction with the Fracture Intervention Trial. On 08-MAY-98 the patient was placed on therapy with alendronate or control, tab. Concomitant therapy included ibuprofen, tab, 200 mg, daily for the treatment of arthritis and calcium carbonate/cholecalciferol. On 20-SEP-98 the patient presented with hematemesis and melena and was hospitalized with a bleeding gastric ulcer. On 20-SEP-98 therapy with alendronate or control and ibuprofen was discontinued. She was given 2 units of blood and started on sucralfate and lansoprazole.</p>			
(Continued on Additional Page)			
6. Relevant tests/laboratory data, including dates			
Unknown			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
CONCURRENT CONDITIONS: arthritis			

<b>C. Suspect medication(s)</b>			
1. Name (give labeled strength & mfr/labeler, if known)			
# 1 TAB FOSAMAX 5 mg			
# 2 TAB ibuprofen 200 mg			
2. Dose, frequency & route used		3. Therapy dates (from/to) (if unknown, give duration)	
# 1 5 mg/DAILY/PO		# 1 05/08/98 - 09/20/98	
# 2 200 mg/DAILY/PO		# 2 10/15/97 - 09/20/98	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced.	
# 1 osteoporosis		yes no N/A unk	
# 2 arthritis		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	
6. Lot # (if known)		7. Exp date (if known)	
# 1 _____		# 1 _____	
# 2 _____		# 2 _____	
8. Event reappeared after reintroduction		yes no N/A unk	
# 1 _____		<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
# 2 _____		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	
9. NDC # - for product problems only (if known)			
Unknown			
10. Concomitant medical products and therapy dates (excluded treatment of event)			
calcium carbonate (+) vitamin d 04/16/98-Cont			

<b>G. All manufacturers</b>	
1. Contact office - name/address	2. Phone Number
Merck Human Health Division Merck & Co., Inc. P.O. Box 4 West Point, PA 19486-0004	(610)397-2416
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input checked="" type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input checked="" type="checkbox"/> health professional	
<input type="checkbox"/> user facility	
<input type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other:	
4. Date received by manufacturer (mo/day/yr)	5. (ANDA # 20560)
09/24/98	IND [REDACTED]
6. If IND, protocol #	PLA #
0510011	pre-1938 <input type="checkbox"/> yes
7. Type of report	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input checked="" type="checkbox"/> initial <input type="checkbox"/> Follow-up# _____	
8. Adverse event term(s)	9. Mfr. report number
HEMORRHAGIC GASTRIC ULCER	WAES 98094078

<b>E. Initial reporter</b>			
1. Name, address & phone #		Unknown Phone #	
Unknown		United States	
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA.	
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

OCT 14 1998



**B. Adverse event or product problem**

**5. Describe event or problem**

Subsequently, the patient recovered and was discharged from the hospital on 22-SEP-98. The reporting physician felt that the bleeding gastric ulcer was possibly related to therapy with alendronate or control and ibuprofen. Additional information has been requested. The record for this patient was unblinded on 05-OCT-98. The patient was found to be on alendronate, 5 mg daily.

OCT 14 1998



WAES Number: 98094078  
Suspect Drug: alendronate sodium  
Evaluation: hemorrhagic gastric ulcer  
Date: 10/08/98

PAGE 1

Previous Submissions

<u>WAES Number</u>	<u>Date(s) Sent To FDA</u>
96044148	04/24/96 05/03/96 06/10/96
97024146	03/13/97 05/13/97

OCT 14 1998

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY Individual Safety Report  
by health professional  
events and product



\*3144474-5-00-01\*

Page \_\_\_ of \_\_\_

### A. Patient information

1. Patient identifier 982420024 In confidence	2. Age at time of event: 41 or Date of birth: [REDACTED]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ___ lbs or 125 kgs
---	---	---	---------------------------------------

### B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 8/30/98

4. Date of this report (mo/day/yr) 8/31/98

5. Describe event or problem

PT WAS ADMITTED FROM ER TO SICU C/O DIZZINESS Hgb 4.24 PRIOR HISTORY INCLUDED MALARIA FOR 3 DAYS 1 WEEK AGO. PT WAS TAKING ADUIC 8 TABS/DAY FOR ARTHRITIS. PT REQUIRED 8 UNITS PRBC. ALSO PREGNANT 9.0 WAS INITIATED PT WILL BE SCOPED TO LOCATE THE SITE OF BLEEDING.

6. Relevant tests/laboratory data, including dates

ADMISSION 8/30 Hgb 4.24  
HCT 14.4

8/31 Hgb 9.0  
HCT 23.1

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PLD 6 YEARS AGO  
Φ ETH  
Φ TOBACCO

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 ADUIC 200MG

#2

2. Dose, frequency & route used

#1 HOME MED

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1

#2

4. Diagnosis for use (indication)

#1 ARTHRITIS

#2

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

### D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

### E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[REDACTED] PHARM

2. Health professional?  yes  no

3. Occupation

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

FDA CTU 91155

OCT 19 1998  
MEDWATCH CTU

**Individual Safety Report**



For **VOLUNTARY** reporting  
 health professionals of adverse  
 events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
 See OMB statement on reverse

FDA Use Only

Triage unit  
 sequence # **93642**

Page **1** **CDER CDER CDER**

**A. Patient information**

1. Patient identifier <b>804789</b> In confidence	2. Age at time of event: <b>74yo</b> or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	---	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/ malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization (initial or prolonged)	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (month/year) **5/26/98**

4. Date of this report (month/year) **11/23/98**

5. Describe event or problem

Pt came to our ER on 5/25/98 c/o nausea, vomiting, light headedness, weakness, 3 tarry black stools where she was found to be slightly hypotensive & obvious melanic stool, anemic, & thrombocytopenic. She was admitted. Her  $pl_t = 4000$ . Pt had been taking Aleve & Advil OTC for arthritis. Pt had acute GI bleed <sup>2 days to NSAID use</sup> → upper GI bleed showed normal esophagus & blood in fundus of stomach, gastritis, & ulcerations. She was felt to have thrombocytopenia (severe) secondary to her NSAIDs. A bone marrow was done & showed plenty of megakaryocytes. By time of discharge, she was feeling better. She was treated with steroids during hospitalization. Pt was discharged home on 6/11/98 w/ advice not to treat w/ OTC NSAIDs.

6. Relevant tests/laboratory data, including dates

Date	Plt	Hgb	Hct	BUN	SCr
5/25	4000	8.8	26.8		
1645		6.8	20.8	34	0.5
2300		8.6	25.7	33	0.3
5/26 615		~1600	~10,000	~9.2	~26.8
5/28	54,000				

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Caucasian  
 Hx of tobacco abuse: 2 packs/day - none since 71  
 Hx of alcohol use: 2 mixed drinks/day  
 Med Hx (past): pneumonia '71, GI bleed 10yrs ago ('88)

**FDA** Mail to: **MEDWATCH** or FAX to:  
 5600 Fishers Lane 1-800-FDA-0178  
 Rockville, MD 20852-9787

FDA Form 3500 (8/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 **Advil 200mg tablet Whitehall ADVIL**

#2 **Aleve tabs Proctor & Gamble**

2. Dose, frequency & route used

#1 **200mg po 2-3x/d**

#2 **200mg 2 tabs/day**

3. Therapy dates (if unknown, give duration) (month or best estimate)

#1 **~1 month**

#2 **~1 month**

4. Diagnosis for use (indication)

#1 **Pain**

#2 **Pain**

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 **unk**

#2 **unk**

7. Exp. date (if known)

#1 **unk**

#2 **unk**

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

**- unk -**

10. Concomitant medical products and therapy dates (exclude treatment of event)

**Ø prescription meds**

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (month/year)

6. model #

7. If implanted, give date (month/year)

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

**Pharmacist**  
**Medical Center Pharmacy**  
**St**

2. Health professional?  yes  no

3. Occupation **Pharmacist**

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

Individual Safety Report



\*3168894-1-00-01\*

**MEDV**

THE FDA MEDICAL PRO...

Company

Mfr report # <b>USA005544</b>
JF/Diet report #
FDA Use Only

**A. Patient information**

1. Patient identifier <b>SB112.0786.0</b> 004 in confidence	2. Age at time of event: <b>31 yrs</b> or Date of birth: [redacted]	3. Sex: <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or <b>147.4 kgs</b>
--	--	--	--

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) **11/11/98**

4. Date of this report (mo/day/yr) **12/04/98**

5. Describe event or problem

**Gastrointestinal bleed**

USA Clinical Protocol SB112 ("AMMO Study" site #0785, patient #0004, initials [redacted]: A 16 week open label trial to evaluate the weight loss efficacy of Meridia when used in accordance with labeling recommendations in physician practice settings. A 31 year old female patient (\*BMI=48.2) with a history of peptic ulcer with gastrointestinal bleed (1996), a three pack year tobacco history as she smokes 1 and 1/2 packs of cigarettes daily and has done so for two years and is known to be self-medicating, as needed, with non-steroidal anti-inflammatory, Ibuprofen, initiated Meridia 10 mg daily for weight loss on 23-Sept-1998. On 9-Nov-1998 (study day 48) she had abdominal pain \*

6. Relevant tests/laboratory data, including dates

**09-Nov-1998 BUN and Creatinine Ratio 2.2 (elevated)**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**History of non-steroidal anti-inflammatory use for pain on a as needed basis. History of peptic ulcer (1996) with gastrointestinal bleed responded to Prilosec (proton pump inhibitor)**

**Risk factor(s): Smokes 1 1/2 pack per day \***

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 **Meridia**

#2 **ibuprofen**

2. Dose, frequency & route used

#1 **10 MG OD PO**

#2 **1 TAB PRN PO**

3. Therapy dates (if unknown, give duration from/to (or best estimate))

#1 **23-SEP-98 to 13-NOV-98**

#2 **UNK to NI**

4. Diagnosis for use (indication)

#1 **weight loss**

#2 **pain**

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 **UNK**

#2 **UNK**

7. Exp. date (if known)

#1 **Unknown**

#2 **Unknown**

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # - for product problems only (if known)

#1 **NI**

#2 **NI**

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: none Dates:

**G. All manufacturers**

1. Contact office - name/address (& mfring site for devices)

**Knoll Pharmaceutical Company**  
3000 Continental Drive - North  
Mount Olive, New Jersey 07828-1234

2. Phone number (973) 426-2600

3. Report source (check all that apply)

foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer (mo/day/yr) **11/17/98**

5. (A)NDA # **20-632**

IND # \_\_\_\_\_  
PLA # \_\_\_\_\_  
pre-1938  yes  
OTC product  yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day  15-day  
 10-day  periodic  
 Initial  follow-up # \_\_\_\_\_

8. Adverse event term(s)  
**GASTROINTESTINAL HAEMORRHAGE NOS**

9. Mfr. report number  
**USA005544**

**E. Initial reporter**

1. Name, address & phone #

[redacted] Consultants  
[redacted] Suite [redacted]  
[redacted] USA \*

DFC 07 1998

2. Health professional?  yes  no

3. Occupation  
+

4. Initial reporter also sent report to FDA  yes  no  unk

**FDA**

Domain Facsimile of  
FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.  
Item completed on continuation pages.

DFC 08 1998

Individual Safety Report



\*3168094-1-00-02\*

cal Company

MED WATCH	A.1. Patient Identifier SB112.0786.0004 [REDACTED]	ber USA005544	Page 2 of 2
-----------	---	------------------	-------------

B.5. Describe event or problem

[continuation:] described as a hard knot under the umbilicus and she had fresh blood in vomitus and in stools. The only abnormal laboratory value for bloodwork drawn on 09-Nov-1998 was an elevated ratio of BUN to creatinine of 2.2. On 11-Nov-1998 (study day 50) she was diagnosed with a gastrointestinal bleed. Treatment given, if any, is unknown. She stopped taking Meridia on 13-Nov-1998. The gastrointestinal bleed resolved on 14-Nov-1998. She continues to have abdominal pain. No follow-up lab work is available at the time of this report. The investigator considered the event to be immediately life threatening and possibly related to Meridia, ibuprofen and/or smoking. However, the investigator added the gastrointestinal bleed stopped when the patient discontinued the Meridia even though she continued on Ibuprofen.

\*BMI= baseline body mass index

B.7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:] for two years  
Race: CAUCASIAN

E.1. Name, address & phone #

[continuation:] Phone: [REDACTED]

E.3. Occupation

STUDY INVESTIGATOR

DEC 07 1998

DEC 07 1998

Individual Safety Report



\*3169681-7-00-01\*

VOLUNTARY reporting  
health professionals of adverse  
events and product problems  
CDER

Page \_\_\_ of \_\_\_

CDER

Form Approved OMB No. 0910-123 Expires 12/31/94 See OMB statement on reverse

FDA Use Only  
Trace unit sequence # **93920**

**A. Patient information**

1. Patient identifier: [redacted] In confidence

2. Age at time of event: \_\_\_\_\_ or Date of birth: \_\_\_\_\_

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death (m/d/yyyy)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: Severe

3. Date of event (m/d/yyyy): 2/13/94

4. Date of this report (m/d/yyyy): 6/12/98

5. Describe event or problem:  
GI Bleed  
  
Tx: Pepcid 20mg @ 12

6. Relevant tests/laboratory data, including dates:  
Hct-23 → 3#  
4 units of Bld  
 REC'D. DEC 09 1998  
 MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
KDA - Tylenol (bladder irritation)  
Duodenicular dz.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
 #1 Ibuprofen IBUPROFEN  
 #2 \_\_\_\_\_

2. Dose, frequency & route used:  
 #1 200mg Po PRN  
 #2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (m/d/yyyy) (or best estimate):  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

4. Diagnosis for use (indication):  
 #1 Pain  
 #2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

7. Exp. date (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

8. Event reappeared after reintroduction:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only): #1 \_\_\_\_\_ #2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event):

**D. Suspect medical device**

1. Brand name: \_\_\_\_\_

2. Type of device: \_\_\_\_\_

3. Manufacturer name & address: \_\_\_\_\_

4. Operator of device:  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (m/d/yyyy): \_\_\_\_\_

6. Model # \_\_\_\_\_  
 Catalog # \_\_\_\_\_  
 Serial # \_\_\_\_\_  
 Lot # \_\_\_\_\_  
 Other # \_\_\_\_\_

7. If implanted, give date (m/d/yyyy): \_\_\_\_\_

8. If explanted, give date (m/d/yyyy): \_\_\_\_\_

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event):

**E. Reporter** [redacted] MS, RPh

1. Name, address: Department of Pharmacy  
 [redacted] Hospital  
 [redacted] Ave

2. Health professional?  yes  no

3. Occupation: RPh

4. Also reported to:  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

**FDA** Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (8/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 93920

# Individual Safety Report

For VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse



\*3169865-8-00-01\*

Page CDER of CDER

CDER

FDA Use Only (placement)

Triage unit sequence # 94016

**A. Patient Information**

1. Patient Identifier: [redacted] In confidence

2. Age at time of event: [redacted] or Date of birth: [redacted]

3. Sex:  female  male

4. Weight: 69 lbs or kg

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):

death (m/day/yr)  life-threatening  hospitalization (initial or prolonged)

disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other: SEVERE

3. Date of event (m/day/yr): 11/4/97

4. Date of this report (m/day/yr): 2/7/98

5. Describe event or problem

1 episode hematemesis @ Home another at ER P-100 BP 93/70

Treatment: IV PEPcid, p.o. prilosec EGD + epinephrine CAUTERY fluid replacement I NS 0.9% 2U PrBC

6. Relevant tests/laboratory data, including dates

H/H ADMIT 12.9/36

EGD EVIDENT for esophageal + gastric ulcers

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

AAA repair 1985 (+ MOD ETOH)

Peptic ulcers 1950s

ALLERGIES: Sulf

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 ASA ASPIRIN

#2 ADVIL

2. Dose, frequency & route used

#1 81mg PO QD

#2 200mg 2-4 tabs tid

3. Therapy dates (if unknown, give duration from/to (or best estimate))

#1

#2

4. Diagnosis for use (indication)

#1 SELF-MED

#2 LOW BACK PAIN

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  lay user/patient  other:

5. Expiration date (m/day/yr)

6. model # 681593

catalog #

serial # XXXXXXXXXXXX

lot #

other #

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on (m/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter**

1. Name, address

[redacted] MS, RPh  
Department of Pharmacy  
[redacted] Hospital  
[redacted] Ave

2. Health professional?  yes  no

3. Occupation RPh

4. Also reported to

manufacturer  user facility  distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (5/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 94016



16-JUL-1998-1060

**MEDWATCH**  
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



\*3186142-X-00-01\*



McNEIL CONSUMER PRODUCTS COMPANY  
FORT WASHINGTON, PA 19034

UP/Date report #  
\_\_\_\_\_  
FDA use only

Page \_\_\_\_ of \_\_\_\_

<b>A Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient identifier Unknown In confidence	2. Age at time of event: or 5 yrs Date of birth:	3. Sex ( ) female ( ) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Motrin (ibuprofen) Suspension #2			
<b>B Adverse event or product problem</b>				2. Dose, frequency & route used #1 unknown dose, po #2			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown #2			
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage (X) other: recovered				4. Diagnosis for use (indication) #1 unknown #2			
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 05/14/98		5. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
6. Describe event or problem Notification via company sales representative of pediatric gastroenterologist report of gastric irritation allegedly associated with the use of ibuprofen in a patient.  Additional information received 5/13/98: Pediatric gastroenterologist reports a 5 or 6 year-old patient was taking unknown doses of Motrin® Suspension for 4 or 5 days and developed HEMATENESIS and gastric ulceration (STOMACH ULCER). Patient was admitted to hospital and an endoscopic examination performed. Patient recovered and was discharged after an unspecified period of time. No further information was provided.				5. Event abated after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 ( ) Yes ( ) No ( ) N/A			
6. Relevant tests/laboratory data, including dates unknown				8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				9. NDC # - for product problems only (if known) -			
				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
<b>G All manufacturers</b>							
1. Contact office - name/address (& mailing site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-233-7820		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer (X) health professional ( ) user facility ( ) company representative ( ) distributor ( ) other:	
4. Date received by manufacturer (mo/day/yr) 05/08/98				5. (A) NDA # 19-842 NDA # PLA # pre-1938 ( ) Yes OTC product ( ) Yes			
6. N IND, protocol #				7. Type of report (check all that apply) ( ) 5-day ( ) 15-day ( ) 10-day (X) periodic (X) initial ( ) follow-up #			
8. Mfr. report number 0978530A				8. Adverse event term(s) ULCER STOMACH HEMATENESIS			
<b>F Initial reporter</b>							
1. Name, address & phone # _____ _____ P.O. Box _____ _____							
2. Health professional? (X) Yes ( ) No		3. Occupation gastroenterolog		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

00 000006

JUL 17 1998



20-JUL-1998-1474

\*3186468-X-00-01\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FORT WASHINGTON, PA 19034

Page \_\_\_ of \_\_\_

as by FDA on 11/15/93

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Unknown In confidence	2. Age at time of event: adult Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Motrin IB Tablets #2			
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage (X) other: recovered				2. Dose, frequency & route used #1 600 mg, daily, po #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown #2	
				4. Diagnosis for use (indication) #1 prior to practice per athletic coach #2		5. Event abated after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 ( ) Yes ( ) No ( ) N/A	
3. Date of event 1997 (mo/day/yr)		4. Date of this report 05/13/98 (mo/day/yr)		6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
5. Describe event or problem  Notification via company sales representative of pediatric gastroenterologist report of gastric irritation allegedly associated with the use of ibuprofen Tablets in a teenage patient. Patient was taking 3 tablets of ibuprofen before practice every day as advised by his athletic coach.  Additional information received 5/13/98: Pediatric gastroenterologist reports in 1997, patient was taking 200 mg Motrin® Tablets for an unknown duration. Patient passed out (SYNCOPE), was taken to hospital, and found to be anemic (ANEMIA). Patient was admitted to hospital. An endoscopy was performed and a DUODENAL ULCER found. Patient recovered and was discharged after an unspecified period of time. No further information was provided.				8. NDC # - for product problems only (if known) - -			
				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
6. Relevant tests/laboratory data, including dates unknown				G. All manufacturers			
				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-233-7820	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				4. Date received by manufacturer (mo/day/yr) 05/08/98		5. (A) NDA # 19-012 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
				6. If IND, protocol #		7. Type of report (check all that apply) ( ) 5-day ( ) 15-day ( ) 10-day (X) periodic (X) initial ( ) follow-up #	
8. Adverse event term(s) ULCER DUODEN ANEMIA SYNCOPE				E. Initial reporter			
				1. Name, address & phone # [REDACTED] MD PO Box [REDACTED] [REDACTED]			
2. Health professional? (X) Yes ( ) No		3. Occupation gastroenterolog		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

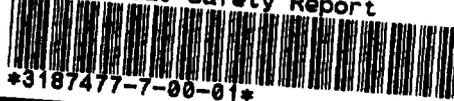
00 000045

JUL 21 1998



16-JUL-1998-0957

**MEDWATCH**  
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



\*3187477-7-00-01\*

McNEIL CONSUMER PRODUCTS COMPANY  
FORT WASHINGTON, PA 19034

Page \_\_\_ of \_\_\_

FDA use only

A. Patient information				C. Suspect medication(s)					
1. Patient identifier [redacted] In confidence	2. Age at time of event: 34 mo or Date of birth: [redacted]	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Children's Motrin Ibuprofen Oral Suspen #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 2.5 days #2			
2. Dose, frequency & route used #1 100 mg, q4h, po #2				4. Diagnosis for use (indication) #1 high fever #2		5. Event abated after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 ( ) Yes ( ) No ( ) N/A			
6. Lot # (if known) #1 Unknown #2				7. Exp. date (if known) #1 Unknown #2		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
9. NDC # - for product problems only (if known) -				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown					
1. X Adverse event and/or Product problem (e.g., defects/malfunctions) 2. Outcomes attributed to adverse event (check all that apply) ( ) death (ma/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage (X) other: recovered				3. Date of event 4/98 (ma/day/yr)				4. Date of this report 05/12/98 (ma/day/yr)	
5. Describe event or problem Notification via company sales representative of physician report of MELENA & HEMATEMESIS allegedly associated w/the use of Children's Motrin® Ibuprofen Oral Suspension in a male patient. According to physician, mother gave patient Children's Motrin 100 mg every 4 hours primarily on empty stomach for a high fever. Two & one-half days later, patient taken to the emergency room w/blood in stool, bleeding from mouth, & vomiting. Patient sent to 2nd hospital, seen by pediatric gastroenterologist, admitted & endoscopy performed. Addl info rec'd 5/13/98: Pediatric gastroenterologist reports patient received a blood transfusion & was treated w/PEPCID® IV for two days, then PRILOSEC®. Endoscopy showed ulcerations in stomach (STOMACH ULCER). Addl info rec'd 6/19/98: Discharge form from hospital indicates patient rec'd multiple 100 mg doses of Motrin over 4 day period w/minimal food intake. Hematemesis x3 prior to admission. Patient admitted to hospital on 4/4/98. On 4/5/98, patient hemodynamically stable & discharged w/principle diagnosis of hematemesis & GASTRITIS.				6. Relevant tests/laboratory data, including dates On 4/5/98: Hct=12.8, Hgb=36.3; EGD reportedly showed ulcerations in stomach, biopsy results not provided				7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown	
6. All manufacturers				1. Contact office - name/address (& mfrng site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-233-7820	
4. Date received by manufacturer (ma/day/yr) 05/08/98				5. (A) NDA # 20-516 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer (X) health professional ( ) user facility ( ) company representative ( ) distributor ( ) other:			
6. # IND, protocol #				7. Type of report (check all that apply) ( ) 5-day ( ) 15-day ( ) 10-day (X) periodic (X) initial ( ) follow-up #		8. Adverse event term(s) ULCER STOMACH MELENA HEMATEMESIS GASTRITIS			
9. Mfr. report number 0977361A				E. Initial reporter					
1. Name, address & phone # [redacted], MD P.O. Box [redacted]				2. Health professional? (X) Yes ( ) No				3. Occupation gastroenterolog	
4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk									



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

JUL 17 1998

00 000063



Patient information

1. Patient Identifier	2. Age at time of event: UNK	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or kg
In confidence	Date of birth:		

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product Problem (e.g. defects/malfunctions)	
2. Outcome attributed to adverse event (check all that apply)	<input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input checked="" type="checkbox"/> Required intervention to prevent permanent impairment/damage <input checked="" type="checkbox"/> Other: <b>MEDICALLY SIGNIFICANT</b>
<input type="checkbox"/> Death <input type="checkbox"/> Life-Threatening (mo/day/yr) <input type="checkbox"/> Hospitalization - initial or prolonged	
3. Date of event (mo/day/yr) 02/07/1999	4. Date of this report (mo/day/yr) 02/12/1999

5. Describe event or problem  
**A report of GI hemorrhage was received. A female patient was hospitalized and received front loaded tPA and was started on a heparin drip on 06-Feb-1999. She continued to have chest pain and was transferred to Memorial. On 07-Feb the chest pain was continuing and she received Integrilin. She was also receiving heparin at the time. At some time during the day she developed melena and was transfused with 2 units of blood. She was diagnosed with gastrointestinal bleeding considered to be related to NSAID consumption as she had been taking copious amounts of Advil for back pain prior to mission.**

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
**DIABETES; SMOKING; HAD BEEN TAKING COPIOUS AMOUNTS OF ADVIL FOR BACK PAIN**

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
# 1	<b>INTEGRILIN (EPTIFIBATIDE) INJECTION INJECTABLE SOLUTION</b>	# 1	<b>02/07/1999- --/--/--</b>
# 2	<b>ADVIL</b>	# 2	
2. Dose, frequency & route used		4. Diagnosis for Use (indication)	
# 1	<b>INTRAVENOUS</b>	# 1	<b>CHEST PAIN</b>
# 2		# 2	<b>BACK PAIN</b>
6. Lot # (if known)		7. Exp. date (if known)	
# 1		# 1	
# 2		# 2	
9. NDC # - for product problems only (if known)		5. Event abated after use stopped or dose reduced	
		# 1	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
		# 2	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
		8. Event reappeared after reintroduction	
		# 1	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
		# 2	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event) <b>HEPARIN ; RT-PA</b>			

G. All manufacturers

1. Contact office-name / address (& mailing site for devices)		2. Phone Number <b>650-244-6800</b>	
<b>COR THERAPEUTICS, INC. 256 EAST GRAND AVENUE SOUTH SAN FRANCISCO, CA 94080</b>		3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> consumer <input type="checkbox"/> other:	
4. Date received by manufacturer (mo/day/yr) <b>02/12/1999</b>	5. (A) NDA # <b>20-718</b> IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	6. Adverse Event Term(s) <b>MELAENA</b>	
6. If IND, protocol #	7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up#	9. Mfr. report number <b>INT1990046</b> <b>MAR 12 1999</b>	

E. Initial reporter

1. Name, address, and phone # [REDACTED] HOSPITAL [REDACTED] UNITED STATES		M.D.	[REDACTED]
2. Health Professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation <b>MEDICAL DOCTOR</b>	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

Individual Safety Report



\*3225666-3-00-01\*

for VOLUNTARY reporting  
by health professionals of adverse  
events and product problems

CDER  
CDER

FDA Use Only  
Triage unit  
sequence # **99836**

Page \_\_\_ of \_\_\_

**A. Patient information**

1. Patient identifier <b>8049</b> confidence	2. Age at time of event: or Date of birth: <b>70</b>	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ___ lbs or ___ kgs
--	---	---	---------------------------------------

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (m/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization (initial or prolonged)	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/day/yr) **11/17/98**

4. Date of this report (m/day/yr) **11/20/98**

5. Describe event or problem

Patient had black stools since Sunday 11/15/98 - came into the ER on 11/17/98 - hypotensive, black stool, ↓ HCT. Had EGD performed - found an ulcer on the bulb of the duodenum, duodenitis, gastritis. Patient had a ⊕ CLO test for H. pylori. Started on Lansoprazole and triple therapy for H. pylori.

**DSS**

MAR 20 1999

ADVERSE EVENT REPORTING SYSTEM

6. Relevant tests/laboratory data, including dates

HCT	
11/17/98	40
11/17/98	32
11/20/98	37

baseline HCT > 6 months prior 47

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Sleep Apnea

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) (m/day/yr) (or best estimate)
#1 Ibuprofen 200mg	#1 6-8 tablets QWK	#1 ~ several months
#2 Aspirin 325mg	#2 2-3 tablets QWK	#2 ~ several months
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 Aches/Pains	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply	
#2 Heart	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> does not apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> does not apply
9. NDC # (for product problems only)		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
None.		

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

REC'D.  
MAR 20 1999

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (m/day/yr)

6. Model # **MEDWATCH CTU**

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on (m/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

CLINICAL PHARMACOLOGIST  
V.A. MEDICAL CENTER  
500 Foothill Drive  
SALT LAKE CITY, UT 84143

2. Health professional?  Occupation: **RPh**

3. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

Form 3500 (6/93)  
**99836**

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



\*3230706-1-00-01\*

THE FDA MEDICAL PRODUCTS REPORTING SYSTEM

Voluntary reporting by health care professionals of adverse and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse

FDA Use Only H Pad

Triage unit sequence #

100251

Age / Gender CDER

CDER

A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 40 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------------	--	---	---

B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> Hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 2/19/99

4. Date of this report (mo/day/yr) 3/23/99

5. Describe event or problem

Admitted to hospital via ER w/ chief complaint Rectal Bleeding / Vomiting / Diarrhea "Passed 3 tablespoons of Blood" the night prior to Admission

ER Temp 100.2  
BP 100/75  
Pulse 96

Discharged 2/22/99

6. Relevant tests/laboratory data, including dates

Stool Culture - Normal

REC'D.

MAR 5 1999

MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Ibuprofen (OTC)

#2

2. Dose, frequency & route used

#1

#2

3. Therapy dates (if unknown, give duration) (from/to or best estimate)

#1 3 days

#2

4. Diagnosis for use (indication)

#1 URI

#2

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

Tylenol

Atenolol 25mg daily

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS

APR 1 1999

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (mo/day/yr)

6. ADVERSE EVENT REPORTING SYSTEM

model #

catalog #

serial #

lot #

other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[Redacted]

2. Health professional?  yes  no

3. Occupation Pharmacist

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



\*3218777-0-00-01\*

**VOLUNTARY** reporting  
by professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **104272**

Page **CDER**

*CDER*  
*All*

**A. Patient information**

1. Patient identifier: **9710**  
 2. Age at time of event: **43**  
 or Date of birth: \_\_\_\_\_  
 3. Sex:  female  male  
 4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)  
 2. Outcomes attributed to adverse event (check all that apply):  
 death (mo/day/yr)  life-threatening  hospitalization - initial or prolonged  
 disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other: \_\_\_\_\_

3. Date of event (mo/day/yr): **12/30/98**  
 4. Date of this report (mo/day/yr): **12/31/98**

5. Describe event or problem:  
 Pt is a 44 year old male with a history of esophagitis secondary to NSAID use. He was brought to VA ER 4/6 days of dizziness, back pain, N/V of brown emetic (coffee ground like emesis), along with fever & chills. He reports dark urine and ↓ oral intake. Acute upper GI bleed suspected most probably from CTC Motrin + Darvon use for back pain. Pt given Prevacid, IV Sandostatin + transfused 2u PRBC when admitted to MICU.

6. Relevant tests/laboratory data, including dates:  
 Admit Hct = 27.3  
 137/98/92 < 99  
 (6.3) (21) (9.4)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
 Sulfonamide allergy

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
 #1 **Motrin (IBU)**  
 #2 \_\_\_\_\_  
 2. Dose, frequency & route used:  
 #1 **200mg prn**  
 #2 \_\_\_\_\_  
 3. Therapy dates (if unknown, give duration) from to (or best estimate):  
 #1 \_\_\_\_\_ #2 \_\_\_\_\_  
 4. Diagnosis for use (indicator):  
 #1 **back pain**  
 #2 \_\_\_\_\_  
 5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply  
 6. Lot # (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_  
 7. Exp. date (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_  
 8. Event reappeared after reintroduction:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply  
 9. NDC # (for product problems only): \_\_\_\_\_  
 10. Concomitant medical products and therapy dates (exclude treatment of event): \_\_\_\_\_

**D. Suspect medical device**

1. Brand name: \_\_\_\_\_  
 2. Type of device: \_\_\_\_\_  
 3. Manufacturer name & address: \_\_\_\_\_  
 4. Operator of device:  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_  
 5. Expiration date (mo/day/yr): \_\_\_\_\_  
 6. Model #: \_\_\_\_\_  
 7. If implanted, give date (mo/day/yr): \_\_\_\_\_  
 8. If explanted, give date (mo/day/yr): \_\_\_\_\_  
 9. Device available for evaluation? (Do not send to FDA):  
 yes  no  returned to manufacturer on (mo/day/yr): \_\_\_\_\_  
 10. Concomitant medical products and therapy dates (exclude treatment of event): \_\_\_\_\_

**E. Reporter (see confidentiality section of this form)**

1. Name, address & phone #:  
**VAMC**  
**1030 Jefferson Ave**  
**Memphis, TN 38104**  
**JUN 10 1999**  
 2. Health professional?  yes  no  
 3. Occupation: **PharmD**  
 4. Also reported to:  
 manufacturer  
 user facility  
 distributor  
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
 5600 Fishers Lane  
 Rockville, MD 20852-9787  
 or FAX to:  
 1-800-FDA-0178

**CTU104272**

Individual Safety Report



\*3279002-7-00-01\*

FDA MEDICAL PRODUCTS REPORTING PROGRAM

**VOLUNTARY** reporting  
 by health professionals of adverse  
 events and product problems

Page 1 of 1 CDER

Form Approved CMS No. 0-110-0291 Expires 12/31/94  
 See OMB statement on reverse

FDA Use Only - N Pdc  
 Triage unit sequence # 104301

**A. Patient Information**

1. Patient identifier # 770  
 2. Age at time of event: 79  
 or \_\_\_\_\_  
 Date of birth: \_\_\_\_\_  
 3. Sex  female  male  
 4. Weight 195 lbs  
 or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

Adverse event and/or  Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply):  
 death  disability  
 life-threatening  congenital anomaly  
 hospitalization - initial or prolonged  required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

5. Date of event (mo, day, yr) 8/3/98  
 4. Date of this report (mo, day, yr) 8/4/98

Describe event or problem:  
*patient presents with a 2 day w/o bright red blood per rectum x 2 on 7/31/98. Family reports patient c/o abdominal pain previously. patient also seen in GI clinic recently + left 2° to abdominal aches. PMH: HTN, osteoarthritis/DJD for which patient admits taking over-the-counter Ibuprofen 3-6 tablets daily. Also takes Salsalate for his arthritis. Inspected abdominal pain 2° to GI bleed.*

6. Relevant tests/laboratory data, including dates

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic renal dysfunction, etc.)  
NRDA

**C. Suspected medication(s)**

1. Name (give labeled strength & ml/r/labeler, if known)  
 #1 Ibuprofen  
 #2 Salsalate

2. Dose, frequency & route used  
 #1 200mg po (3-6 tabs/day)  
 #2 750mg po (2 BID)  
 3. Therapy dates (if unknown, give duration) (from to, or best estimate)  
 #1 1995-98  
 #2 5/2/98-present

4. Diagnosis for use (indication)  
 #1 arthritis  
 #2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

7. Exp. date (if known)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspected medical device**

1. Brand name  
 2. Type of device  
 3. Manufacturer name & address  
 4. Operator of device  
 health professional  
 lay user/patient  
 other

5. Expiration date (mo, day, yr)  
JUN 10 1999  
 6. model # \_\_\_\_\_  
 7. If implanted, give date (mo, day, yr)  
MEDWATCH CTU  
 8. If explanted, give date (mo, day, yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #  
VAMC, 1030 JEFFERSON AVE  
MEMPHIS, TN 38104  
901 523-8990 EXTENSION 7363  
JUN 10 1999

2. Health professional?  yes  no  
 3. Occupation Pharm  
 4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
 5600 Fishers Lane  
 Rockville, MD 20852-9787  
 or FAX to:  
 1-800-FDA-0178

CTU 104301

Individual Safety Report



\*3279013-1-00-01\*

Voluntary reporting  
with professionals of adverse  
events and product problems

Page 1 of 1 - CDER

Form Approved OMB No. 0910-0291 Expires 10/31/99  
See OIRB statement on reverse

FDA Use Only H P 14

Triage unit  
sequence # 104321

**A. Patient Information**

1. Patient identifier # 4743  
 2. Age at time of event: 68  
 or Date of birth: \_\_\_\_\_  
 3. Sex  female  male  
 4. Weight 168 lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

Adverse event and/or  Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply):  
 death  disability  
 life-threatening  congenital anomaly  
 hospitalization - initial or prolonged  required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

5. Date of event (mo/day/yr) 8/3/98  
 6. Date of this report (mo/day/yr) 8/4/98

Describe event or problem:  
 Patient presents with stomach pain and black stools for 1-2 weeks. Patient takes Advil OTC for generalized pain, drinks 2 quarts of beer a day and 1/2 pack cigs. Upper GI bleed suspected & patient given 2 units of PRBC's.

7. Relevant tests/laboratory data, including dates:  
 CBC (Hct = 25.2)  
 Chem 7

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
 NKA

Mail to: MEDWATCH  
 5600 Fishers Lane  
 Rockville, MD 20852-9787  
 or FAX to:  
 1-800-FDA-0178



FDA Form 3500 (6/97)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

**C. Suspect medication(s)**

1. Name (give labeled strength & ml/labeler, if known)  
 #1 Advil  
 #2 \_\_\_\_\_

2. Dose, frequency & route used  
 #1 800mg po TID  
 #2 \_\_\_\_\_  
 3. Therapy dates (if unknown, give duration) (from to or best estimate)  
 #1 3 week prior to admit  
 #2 \_\_\_\_\_

4. Diagnosis for use (indication)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_  
 5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_  
 7. Exp. date (if known)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_  
 10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspected medical device**

1. Brand name  
 2. Type of device

3. Manufacturer name & address  
 4. Operator of device  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_  
 catalog # \_\_\_\_\_  
 serial # \_\_\_\_\_  
 lot # \_\_\_\_\_  
 other # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #  
 VAMC, 1030 JEFFERSON AVE.  
 MEMPHIS, TN 38104  
 901 523-8990 EXTENSION 7363

2. Health professional?  yes  no  
 3. Occupation PharmD  
 4. Also reported to  
 manufacturer  
 user/facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CDER  
 112

REC'D.

JUN 30 1999

MEDWATCH CTU

DSS

JUN 10 1999

ADVERSE EVENT REPORTING SYSTEM

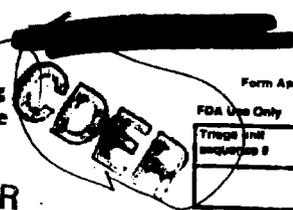


\*3285854-7-00-01\*

**UNLUNATARY** reporting  
of professionals of adverse  
and product problems

Form Approved: OMB No. 0019-0291 Expires: 4/2006  
See OMB statement on reverse  
FDA Use Only  
Trace #  
104779

Page 1 of 1 CDER



**A. Patient information**

1. Patient Identifier: 108016  
In confidence

2. Age at time of event: 68  
or  
Date of birth:

3. Sex:  female  male

4. Weight: 177 lbs or kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death (m/d/yy)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other:

3. Date of event (m/d/yy): 10-1-98

4. Date of this report (m/d/yy): 6-16-99

5. Describe event or problem:  
 Patient was previously admitted to the hospital and found to have a bleeding duodenal ulcer which was cauterized endoscopically. He was discharged on 9-30-98. Subsequently, he did not feel well and took some Advil for low back pain. He came to the Emergency Department on 10-1-98 with complaint of lightheadedness and dizziness. He was readmitted for repeat cauterization and discharged on 10-7-98. Advised to avoid NSAIDs.

6. Relevant tests/laboratory data, including dates:  
 Hgb = 8.6, 7.4 on 10-1-98  
 Stool is guaiac positive. (10-1-98)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
 Patient is Caucasian with a history of hypertension and peptic ulcer. He is a cigarette smoker and a recovering alcoholic. He has an allergy to penicillin.

PLEASE USE BLACK INK

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
 #1 Advil  
 #2

2. Dose, frequency & route used:  
 #1 unspecified  
 #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate):  
 #1 unspecified  
 #2

4. Diagnosis for use (indication):  
 #1 analgesic  
 #2

5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known):  
 #1  
 #2

7. Exp. date (if known):  
 #1  
 #2

8. Event reappeared after reintroduction:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only):  
 -

10. Concomitant medical products and therapy dates (exclude treatment of event):  
 Prilosec, Norvasc, Hytrin

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device:  
 health professional  
 lay user/patient  
 other:

5. Expiration date (m/d/yy)

6. model # REC'D.  
 catalog #  
 serial # JUN 16 1999  
 lot #  
 other # MEDWATCH CTU

7. If implanted, give date (m/d/yy)

8. If explanted, give date (m/d/yy)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on (m/d/yy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name & address: [redacted] Hospital  
 phone # [redacted] ext. [redacted]

2. Health professional?  yes  no

3. Occupation: Pharmacist

4. Also reported to:  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
OR FAX to:  
1-800-FDA-0178

3A Form 3500 (7/98)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



CTU 104779

HR-2

Individual Safety Report



\*3291234-0-00-01\*

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse

or use by user-facilities,  
utors and manufacturers for  
MANDATORY reporting

Mfr report #	98-0169-022	( 98-2708 )
UF/Dist report #		
FDA Use Only		

Page 1 of 1

FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1 Patient identifier	2 Age at time of event: 23 or _____ Date -NI of birth: _____	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 140 lbs -91 kg
----------------------	---	--	-------------------------------

B. Adverse event or product problem

1 <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2 Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> recured intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3 Date of event (mo/day/yr) 10/07/98	4 Date of this report (mo/day/yr) 10/27/98
--------------------------------------	--

5. Describe event or problem  
A 23-year-old female reported that following the occasional use of Advil liqui-gels for 1 month, she experienced severe stomach pain and went to an ER, after taking 1 liqui-gel on 10/7/98. She was hospitalized 10/7/98-10/9/98. She was told that the pain was due to Advil that "made a hole in my stomach". Zantac (ranitidine) was prescribed. At time of reporting she still felt soreness. Medical records were requested. On a follow-up call on 10/21/98 the consumer stated that the soreness has abated and her condition has improved. She is continuing to use Zantac. No further symptoms or sequelae were reported.

6 Relevant tests/laboratory data, including dates  
No information provided.

Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
No additional medical history information provided

No allergy history reported.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	
#1 Advil (R) (Ibuprofen) Liqui-Gels	
#2 -NA	
2 Dose, frequency & route used	
#1 1 liqui-gel prn	
#2 -NA	
3 Therapy dates (if unknown, give duration) (mo/day/yr)	
#1	#2
4 Diagnosis for use (indication)	
#1 headache	
#2 -NA	
5 Event abated after use stopped or dose reduced	
#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6 Lot # (if known)	
#1 3982231	#7 Exp. date (if known) #1 05/00
#2 -NA	#2 -NA
8 Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9 NDC # - for product problems only (if known)	
0573 - 0169 - 20	
10 Concomitant medical products and therapy dates (exclude treatment of event) None reported.	

D. Suspect medical device

1 Brand name	
2 Type of device	
3 Manufacturer name & address	
4 Operator of device	
<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
5 Expiration date (mo/day/yr)	
6 model #	
7 If implanted, give date (mo/day/yr)	
8 If explanted, give date (mo/day/yr)	
9 Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	

E. Initial reporter

1 Name, address & phone #			
P.O. Box _____ United States			
DEC 08 1998			
2 Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3 Occupation -NA	4 Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

P.E. 10/27/98

00-0015

Individual Safety Report



\*3291234-0-00-02\*

Completion of a report does not constitute a statement that medical personnel, user, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service - Food and Drug Administration

(continued)

Refer to guidelines for specific instructions

Page \_\_\_\_\_ of \_\_\_\_\_

FDA Use

F. For use by user facility/distributor—devices only			
1. Check one <input checked="" type="checkbox"/> user facility <input type="checkbox"/> distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (mo/day/yr)		7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	8. Date of this report (mo/day/yr)
9. Approximate age of device	10. Event problem codes (refer to coding manual) patient code: [ ] - [ ] - [ ] device code: [ ] - [ ] - [ ]		
11. Report sent to FDA? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> other: _____ specify	
13. Report sent to manufacturer? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no			
14. Manufacturer name/address			

H. Device manufacturers only	
1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guidelines) <input type="checkbox"/> other: _____	2. If follow-up, what type? <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation
3. Device evaluated by mfr? <input type="checkbox"/> not returned to mfr. <input type="checkbox"/> yes <input type="checkbox"/> evaluation summary attached <input type="checkbox"/> no (attach page to explain why not) or provide code: _____	4. Device manufacture date (mo/yr)
	5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no
6. Evaluation codes (refer to coding manual)	
method	[ ] - [ ] - [ ] - [ ]
results	[ ] - [ ] - [ ] - [ ]
conclusions	[ ] - [ ] - [ ] - [ ]
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> patient monitoring <input type="checkbox"/> relabeling <input type="checkbox"/> modification/adjustment <input type="checkbox"/> other: _____	8. Usage of device <input type="checkbox"/> initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown
9. If action reported to FDA under 21 USC 360(i)(1), list correction/removal reporting number:	

G. All manufacturers	
1. Contact office - name/address (& mailing site for devices)  Whitehall-Robins Medical Department 5 Giralda Farms Madison, NJ                      07940-0871	2. Phone number 973-660-5500
3. Date received by manufacturer (mo/day/yr) 10/11/98	5. (A)INDA #    20-402 IND #            -NA PLA # pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes
4. If IND, protocol #	3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other
6. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	8. Adverse event term(s) ULCER PEPTIC PAIN ABDO
7. Mfr. report number 98-0169-022	

10. <input type="checkbox"/> Additional manufacturer narrative	and/or	11. <input type="checkbox"/> Corrected data
--	--------	---

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Reports Clearance Officer, PHS Hubert H. Humphrey Building, Room 721-B, 200 Independence Avenue, S.W., Washington, DC 20201, ATTN: PRA

and to Office of Management and Budget, Paperwork Reduction Project (0910-0291), Washington, DC 20503

Please do NOT return this form to either of these addresses.

Individual Safety Report



\*3295426-6-00-01\*

Voluntary reporting  
th professionals of adverse  
ts and product problems

CDEF

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse

FDA Use Only

Triage unit  
sequence # **105607**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page L of L

CDEF

**A. Patient information**

1. Patient Identifier: **4225**  
In confidence

2. Age at time of event: \_\_\_\_\_  
or \_\_\_\_\_  
Date of birth: \_\_\_\_\_

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs  
or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death (m/d/yr)

life-threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other: \_\_\_\_\_

3. Date of event (m/d/yr): **3/3/99**

4. Date of this report (m/d/yr): **5/20/99**

5. Describe event or problem

4225: GI BLEED  
87 YOF adm to ED with vomiting, fever, and generalized weakness. While in ED, pt found to have Hgb of 6.7 and guaic positive stool. Pt had been taking Nuprin at home for stump pain (BKA). GI Consult confirmed GI bleed and felt secondary to NSAID use. Pt recvd transfusion and admitted for further treatment

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

- HTN, DM, Anemia, PVD,  
Diverterculitis

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 **IBUPROFEN**

#2 **ASPIRIN**

2. Dose, frequency & route used

#1 **? PO ?**

#2 **? PO ?**

3. Therapy dates (if unknown, give duration)  
(m/d/yr) (or best estimate)

#1 **?**

#2 **?**

4. Diagnosis for use (indication)

#1 **PAIN**

#2 **"**

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**Diltiazem, Sertraline, Gabapentin, Insulin**

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (m/d/yr)

6. model # \_\_\_\_\_

catalog # **REC'D.**

serial # \_\_\_\_\_

lot # **JUL 01 1999**

other # **MEDWATCH CTU**

7. If implanted, give date (m/d/yr)

8. If explanted, give date (m/d/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone # \_\_\_\_\_ PharmD  
Dept. of Pharmacy Services, \_\_\_\_\_  
Hospital \_\_\_\_\_  
\_\_\_\_\_ Street, \_\_\_\_\_  
Phone: (\_\_\_\_\_) \_\_\_\_\_

2. Health professional?  yes  no

3. Occupation **Pharmacist**

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CTU 105607



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-0787

or FAX to:  
1-800-FDA-0178



\*3300887-X-00-01\*

FD-108 (Rev. 12/31/94)

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Mfr report # 98-0150-135 (98-3004) UFDiet report # FDA Use Only

Patient information

1 Patient identifier, 2 Age at time of event: 61, 3 Sex: XX female, 4 Weight: 170 lbs

B. Adverse event or product problem

1 Adverse event and/or Product problem, 2 Outcomes attributed to adverse event, 3 Date of event, 4 Date of this report

Describe event or problem: A physician reported that a 61-year-old female experienced nausea around 12:00 AM on 03-Nov-98 following a 3 week regimen of 1600 mg (total daily dose) Advil tablets...

c Relevant tests/laboratory data, including dates: 11/03/98 (on admission): Hg=12.3 g/dl, Hct=37.5, wbc count=7,500/mcl, platelets=25,000/mcl

JUL 07 1999

Other relevant history, including preexisting medical conditions: Arthritis (duration of history not reported), Thyroid condition (duration of history not reported)

No allergy history reported.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known), 2 Dose, frequency & route used, 3 Therapy dates, 4 Diagnosis for use, 5 Event abated after use, 6 Lot #, 7 Exp. date, 8 Event reappeared after reintroduction, 9 NDC #, 10 Concomitant medical products

D. Suspect medical device

1 Brand name, 2 Type of device, 3 Manufacturer name & address, 4 Operator of device, 5 Expiration date, 6 model #, 7 If implanted, give date, 8 If explanted, give date, 9 Device available for evaluation?, 10 Concomitant medical products

E. Initial reporter

1 Name, address & phone #, M.D., United States

2 Health professional?, 3 Occupation Physician, 4 Initial reporter also sent report to FDA



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



\*3300887-X-00-02\*

This report does not constitute an opinion that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

(continued)

Refer to guidelines for specific instructions

Page \_\_\_\_\_ of \_\_\_\_\_

FDA Only

### F. For use by user facility/distributor—devices only

1 Check one <input type="checkbox"/> user facility <input type="checkbox"/> distributor		2 UF/Dis: report number	
3 User facility or distributor name/address			
4 Contact person		5 Phone Number	
6 Date user facility or distributor became aware of event (mo/day/yr)		7 Type of report: <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	
8 Date of this report (mo/day/yr)		9 Approximate age of device	
10 Event problem codes (refer to coding manual): patient code _____ - _____ - _____ device code _____ - _____ - _____			
11 Report sent to FDA? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no		12 Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> other: _____ (specify)	
13 Report sent to manufacturer? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no		14 Manufacturer name/address	

### H. Device manufacturers only

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guidelines) <input type="checkbox"/> other: _____		2 If follow-up, what type? <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation	
3. Device evaluated by mfr? <input type="checkbox"/> not returned to mfr <input type="checkbox"/> yes <input type="checkbox"/> evaluation summary attached <input type="checkbox"/> no (attach page to explain why not) or provide code _____		4. Device manufacture date (mo/yr)	
5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no		6. Evaluation codes (refer to coding manual) method: _____ - _____ - _____ - _____ results: _____ - _____ - _____ - _____ conclusions: _____ - _____ - _____ - _____	
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> patient monitoring <input type="checkbox"/> relabeling <input type="checkbox"/> modification/adjustment <input type="checkbox"/> other _____		8. Usage of device <input type="checkbox"/> initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/reporting number		10. <input type="checkbox"/> Additional manufacturer narrative and/or 11. <input type="checkbox"/> Corrected data	

### G. All manufacturers

1 Contact office - name/address (& mfring site for devices)  Whitehall-Robins Medical Department 5 Giralda Farms Madison, NJ 07940-0871		2 Phone number 973-660-5500	
3 Date received by manufacturer (mo/day/yr) 11/06/98		4 Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other	
5 If IND, protocol #		6 (A)INDA # 18-989 IND # -NA PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes	
7 Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up # _____		8 Adverse event term(s)  GASTRITIS PANCYTOPENIA HEMATEMESIS	
9 Mfr. report number  98-0150-135			

JUL 07 1999

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building, Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201  
ATTN: PRA

and to  
Office of Management and Budget  
Paperwork Reduction Project (0910-0291)  
Washington, DC 20503

Please do NOT return this form to either of these addresses.

Individual Safety Report



\*3315282-7-00-01\*



Page 1 of 2

Approved by FDA on 12/02/93

Mfr report #	9917096
UF/Dist report #	
FDA Use Only	

\*- indicates item continued

**A. Patient Information**

1. Patient Identifier [REDACTED] in confidence	2. Age at time of event: UNKNOWN or Date of Birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 242.0 lbs or [REDACTED] kg
--	---	---	---

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)	
# 1 FELDENE CAPSULES	
# 2 ADVIL	
2. Dose, frequency & route used	
# 1 ORAL	
# 2 NOT SPECIFIED	
3. Therapy dates (if unknown, give duration) from/to (or best estimates)	
# 1 UNKNOWN	
# 2 UNKNOWN	
4. Diagnosis for use (indications)	
# 1 INDICATION UNKNOWN	
# 2 INDICATION UNKNOWN	
5. Event abated after use stopped or dose reduced	
# 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
UNKNOWN	
# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	
# 1 UNKNOWN	
# 2 UNKNOWN	
7. Exp. date (if known)	
# 1 UNKNOWN	
# 2 UNKNOWN	
8. Event reappeared after reintroduction	
# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
UNKNOWN	
# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
N/A	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
PROVENTIL ---/---/97 - PRESENT	

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)

death (mo/day/yr)

life-threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other: \_\_\_\_\_

3. Date of event UNKNOWN (mo/day/yr)

4. Date of this report 07/28/99 (mo/day/yr)

5. Describe event or problem

THIS IS A FOLLOW-UP REPORT BASED ON INFORMATION RECEIVED BY PFIZER ON 13JUL99. THE INITIAL REPORT WAS SUBMITTED ON 30APR99. THIS FEMALE CONSUMER, WHO IS CURRENTLY 46 YEAR OLD REPORTS THAT SHE TOOK FELDENE (PIROKICAM) A "LONG TIME AGO." THE FELDENE CAUSED BURNING OF HER EARS. SHE DISCONTINUED THE FELDENE AFTER ONE OR TWO DOSES AND THE BURNING EARS RESOLVED. SHE HAS TAKEN ADVIL (IBUPROFEN) AND DEVELOPED GASTRIC REFLUX AND A LESION IN HER ESOPHAGUS, WHICH REQUIRED HOSPITALIZATION. IN MAR98, SHE DEVELOPED BREAST CANCER, SHE HAD A WIDE EXCISION WITH "DUCTAL CARCINOMA IN SITU." AS OF 16APR99, HER BREAST CANCER IS IN REMISSION. ON FOLLOW-UP, THIS PHYSICIAN REPORTS THAT THE PATIENT TAKING FELDENE AND ADVIL AND WAS COMPLAINING OF CHEST PAIN SYMPTOMS. THE PATIENT WAS ADMITTED TO A HOSPITAL FOR CARDIAC AND GASTROINTESTINAL EVALUATIONS. THE RESULT OF CARDIAC EVALUATION WAS NEGATIVE BUT THE RESULT OF GASTROINTESTINAL EVALUATION FOUND THE PATIENT TO HAVE GASTRIC REFLUX, WHICH WAS TREATED WITH PREVACID (LANSOPRAZOLE).

6. Relevant tests/laboratory data, including dates

UNKNOWN

RECEIVED

JUL 30 1999

By \_\_\_\_\_

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)

SYMPTOMS OF LUPUS ERYTHEMATOSUS  
MILD ASTHMA (97)

OTHER:  
- POSITIVE ANTI-NUCLEAR ANTIBODY WITH A LOW TITER.

ALLERGIES:  
- PENICILLIN CAUSES ANAPHYLAXIS  
- CIPROFLOXACIN CAUSES BREATHING PROBLEMS  
- INTRAVENOUS PYELOGRAM DYES CAUSES HIVES  
- ADHESIVE, MOLDS, FUNGUS, MONOSODIUM GLUTAMATE

DSS

AUG 02 1999

**G. All manufacturers**

1. Contact office - name/address (& mailing site for devices)	2. Phone number
PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42 STREET NEW YORK, N.Y. 10017 U.S.A	212-573-3129
4. Date received by manufacturer (mo/day/yr)	5. Report source (check all that apply)
07/13/99	<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	3. NDA # NDA #18-147
N/A	IND # _____ PLA # _____
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-Day <input type="checkbox"/> periodic <input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1	OTC product <input type="checkbox"/> yes
9. Mfr. report number	8. Adverse event term(s)
9917096	CHEST PAIN GASTROINTESTINAL DISORDER VASODILATATION GASTROINTESTINAL DISORDER BREAST CARCINOMA

**E. Initial reporter**

1. Name, address & phone #	
[REDACTED]	
Tel. - [REDACTED]	
2. Health professional?	3. Occupation
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	INFO. TECHNOLOGIST W/LASER
4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



\*3315282-7-00-02\*

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9917096

B7. OTHER RELEVANT HISTORY - Continued

- ASSARATIME; COSMETICS
- DUST MITES
- ADVERSE DRUG EVENTS:
  - SULFA DRUGS CAUSES ITCHING
  - LISINOPRIL CAUSES A DRY COUGH
  - GRISEOFULVIN CAUSES EXTREME VERTIGO
  - ALPRAZOLAM CAUSES HYPERACTIVITY AND MADE HER EMOTIONALLY DISTRAUGHT

STRESS

E1. NAME AND ADDRESS OF REPORTER - Continued

DR. [REDACTED] M.D.  
[REDACTED]  
[REDACTED]

Tel. - [REDACTED]

**DSS**  
AUG 02 1999

RECEIVED  
JUL 30 1999  
[REDACTED]



\*3326451-4-00-01\*

or VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31/99 See OMB statement on reports

FDA User Only

Unique unit sequence # 107894

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page CDER

CDER

A. Patient information

1. Patient identifier [redacted] 2. Age at time of event: 97 3. Sex:  female  male 4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

In confidence Date of birth: \_\_\_\_\_

B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defect/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death  life-threatening  hospitalization - initial or prolonged

disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other: \_\_\_\_\_

3. Date of event (month/year): 6/18/99 4. Date of this report (month/year): 8/14/99

5. Describe event or problem

- Pt admitted w/ upper GI bleed w/ presumed ulcer 2° to Advil use - reported "has been taking a lot of Advil lately".

Required several units of blood + GI intervention. Had a significant ↓ in H+H on admission (5.9 + 16.9, respectively).

	1992	1995	1997	1998	1031	2015
Hgb	5.9	7.0	8.5	9.1	9.9	8.0
Hct	16.9	20.8	24.3	26.8	28.4	24.2

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)

PMH: HTN, heart disease, osteoarthritis, osteoporosis

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Advil 200mg tabs #2 ADVIL

2. Dose, frequency & route used #1 unknown #2 unknown

3. Therapy dates (if unknown, give duration) #1 unknown #2 unknown

4. Diagnosis for use (indication) #1 pain #2

6. Lot # (if known) #1 NA #2

7. Exp. date (if known) #1 NA #2

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

Serzone 50mg BID, Bumex 1mg qd, Lomoxin 0.125mg qd, KCl-10mEq qd, Loprenor 50mg BID

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device  health professional  lay user/patient  other:

5. Expiration date (month/year)

6. model # AUG 16 1999

catalog #

7. If implanted, give date (month/year)

serial # MEDWATCH CTU

lot #

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)  yes  no  returned to manufacturer on \_\_\_\_\_ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Re [redacted] Pharm. D. [redacted] Clinical Pharmacist

1. Name, [redacted] MEDICAL CENTER [redacted] Street [redacted] DSS [redacted] Fax [redacted]

2. Health p [redacted] AUG 17 1999

3. If you are the reporter  yes  no

ADVERSE EVENT REPORTING SYSTEM

FDA Mail to: MEDWATCH 5500 Fishers Lane Rockville, MD 20852-8787 or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 107894





\*3345555-3-00-01\*

Page

of

CDER MRV

109353

**A. Patient information**

1. Patient identifier: 9392  
In confidence

2. Age at time of event: 72  
or  
Date of birth:

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/ malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death (m/day/yr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other:

3. Date of event (m/day/yr): 5/19/99

4. Date of this report (m/day/yr): 8/26/99

5. Describe event or problem

GI bleed

MEG Pain  
melena x 2/day for 3 days PTA  
Dizziness, mild nausea

patient told not to take Ibuprofen + was put on lansoprazole

6. Relevant tests/laboratory data, including dates

HGB	5/20
HCT	8.8
	26.8

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTU 109353

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
 #1 Ibuprofen IBUPROFEN  
 #2 ASA 81mg qd ASPIRIN

2. Dose, frequency & route used  
 #1 81mg qd  
 #2 200mg qid

3. Therapy dates (if unknown, give duration) (m/day/yr for best estimate)  
 #1 →  
 #2 →

4. Diagnosis for use (indication)  
 #1 RA pain  
 #2

5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known)  
 #1  
 #2

7. Exp. date (if known)  
 #1  
 #2

8. NDC # (for product problems only)

9. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

10. Concomitant medical products and therapy dates (exclude treatment of event)  
 Prednisone 5mg qd

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device  
 health professional  
 lay user/patient  
 other:

5. Expiration date (m/day/yr)

6. model #

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on (m/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

STVHCS (119)  
7400 Merton Minter Blvd.  
San Antonio, Texas 78284

2. Health professional?  yes  no

3. Occupation: Pharm D

4. Also reported to  
 manufacturer  
 user facility  
 distributor

if you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH 5800 Fishers Lane Rockville, MD 20852-9787

OR FAX to:

1-800-FDA-1088

RECEIVED





169594

FDA Use Only

Triage unit sequence # 109487

CDER

1. Patient Identifier: [redacted] In confidence

2. Age at time of event: 30  
Date of birth: \_\_\_\_\_

3. Sex:  female  male

4. Weight: 73.4 kgs

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death (mm/dd/yyyy)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (mm/dd/yyyy): 05/11/1999

4. Date of this report (mm/dd/yyyy): 09/10/1999

5. Describe event or problem (up to a total of 6400 characters allowed)  
 The patient is a 30 year old female with history of chronic lower backpain L5-S1 secondary to disc herniation who presents to ER with complaint of vomit containing blood. She also has nausea, dizziness while standing and abdominal pain. Patient has taken diclofenac 50mg bid and also ibuprofen (OTC) 5-6 per day. Patient was admitted and EGD was performed. NSAIDs were discontinued. EGD revealed only some mild gastritis at the duodenal bulb. Patient stabilized and was discharged 5/13/99. She was prescribed Darvocet for her back pain.

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)  
 DSS  
 SEP 13 1999

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)  
 #1 DICLOFENAC / 50MG / ROXANE  
 #2 IBUOFEN / 200MG /

2. Dose/Frequency/Route used  
 #1 50MG / BID /  
 #2 200MG / 5-6QD /

3. Therapy dates (if unknown, give duration)  
 #1 From - To (or best estimate)  
 #2 -

4. Diagnosis for use (separate indications with commas)  
 #1 CHRONIC LOWER BACK PAIN  
 #2 CHRONIC BACK PAIN

5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known) #1 #2  
 #1 #1  
 #2 #2

7. Exp. date (if known) #1 #2

8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only)  
 - -

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mm/dd/yyyy)

6. model # \_\_\_\_\_  
 catalog # SEP 13 1999  
 serial # MEDWATCH CTU  
 lot # \_\_\_\_\_  
 other # \_\_\_\_\_

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)  
 yes  no  returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

1. Name [redacted] phone # [redacted]

Address: 5000 W. NATIONAL AVE  
 VA MED CTR MILWAUKEE, WI 53295

E-mail (for electronic acknowledgement) [redacted]

2. Health professional?  yes  no

3. Occupation: Pharmacist

4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.

CTU 109487



MEDWATCH 5600 Fishers Lane Rockville, MD 20852





\*3375847-3-00-01\*

PRINT DATE: 13-OCT-1999 17:32:48

Approved by FDA on September 17, 1993

# MEDWATCH

## SEARLE

U.S. REPORTING

### Drug Experience Report

Searle Research and Development

Mfr report #	990616-SK909
UFDDist report #	
FDA Use Only	

Page 1 of 3

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information			
1. Patient identifier	2. Age at time of event: 76 Yrs or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 144 lbs or kgs

B. Adverse event or product problem	
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:
<input type="checkbox"/> death (m/d/yyyy)	
<input checked="" type="checkbox"/> life-threatening	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	

3. Date of event (m/d/yyyy)	JUN 10 1999	4. Date of this report (m/d/yyyy)	AUG 9 1999
-----------------------------	-------------	-----------------------------------	------------

5. Describe event or problem  
MEDICALLY SIGNIFICANT

On Jun-11-99 a physician reported a 76 year old female patient started on Celebrex (celecoxib) 200 mg daily for arthritis on May-25-99. On Jun-10-99 she experienced bruising, diarrhea, rectal bleeding and "burgundy-colored stools". A blood test on Jun-10-99 revealed a normal platelet count. Celebrex was discontinued on Jun-10-99 due to these events. Her past medical history is significant for polycythemia vera, heart attack, stroke and colon cancer. Concomitant medications include aspirin 325 mg four times weekly for prevention of heart attack and stroke. This is the second of two reports. The first report is 990616-SK908 (Purpura thrombopenic thrombotic)

Additional information has been requested.

(Follow-Up) JUL 29 1999

On Jul-29-99 a 3500 form and medical records were received. The 3500 form reads: Patient bled from old colon anastomosis. Status post resection of colon due to cancer and a history of polycythemia vera. Physician identified the patient as a 76 year old male.

(continues...)

6. Relevant test/laboratory data, including dates	Jun-10-99: Blood test, normal platelet count.
---	---

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCOMITANT ILLNESSES: MYOCARDIAL INFARCT NOS; CVA; MAL NEOPL INTESTINE NOS; POLYCYTHEMIA VERA; OSTEOARTHRISIS NOS; TOTAL KNEE REPLACEMENT; FX NECK OF FEMUR NOS-CL; CHONDROCALCINOSIS NOS; PART LG BOWEL EXC NEC; AORTOCORONARY BYPASS NOS; HEAD/INK ENDARTERECT NEC; UNILAT IH REPAIR NOS; GASTROINTEST HEMOR NOS; ADE MED/BIOI SUBST NOS

Heart attack  
Stroke

(continues...)

SEARLE Drug Surveillance Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 CELEBREX			
#2 ADVIL			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 200.000 MG QD PO		#1 MAY 25 1999 - JUN 10 1999	
#2 UNKNOWN PO		#2 UNKNOWN	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 OSTEOARTHRISIS NOS		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 PAIN IN JOINT		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 UNK		#1 UNK	
#2 UNK		#2 UNK	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
AMLODIPINE BESYLATE	Unknown	-	Unknown
COLCHICINE	Unknown	-	Unknown
PROPOXYPHENE NAPSYLATE	Unknown	-	Unknown
ACETAMINOPHEN	Unknown	-	Unknown
ASPIRIN	Unknown	-	Unknown

G. All manufacturers	
1. Contact office - name/address	
Dennis P. Miley, M.D. G.D. Searle and Co. 9911 Woods Drive Skokie, Illinois 60077	
2. Phone number	
(847) 581-7874	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
4. Date received by manufacturer (m/d/yyyy)	5. (A) NDA #
JUL 29 1999	20-998
6. If IND, protocol #	IND #
	PLA #
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1 (Rev. No. 1)	OTC product <input type="checkbox"/> yes
9. Mfr. report number	8. Adverse event term(s)
990616-SK909	ANASTOMOTIC ULCERATION Hemorrhagic ECCHYMOSES DIARRHEA

E. Initial reporter	
1. Name, address & phone #	
[Redacted] MD Suite [Redacted] UNITED STATES Telephone Nr: [Redacted]	
2. Health professional?	3. Occupation
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	MD
4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

FOLLOW-UP

990616-SK909

CELEBREX





\*3375847-3-00-03\*

PRINT DATE: 13-OCT-1999 17:32:48

Approved by FDA on September 17, 1993

# MEDWATCH

## SEARLE

U.S. REPORTING

### Drug Experience Report

Searle Research and Development

My report #	990616-SK909
UFDist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 3 of 3

#### B. Adverse event or product problem (continued)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
 Polycythemia vera

(Follow-Up) JUL 29 1999

Medical records received 7-29-99:

- Osteoarthritis
- Left knee replacement September 1998
- Fracture left hip, open reduction internal fixation November 1998
- Pseudogout right knee
- Colon carcinoma, colon resection
- Coronary bypass: 1993
- Cerebrovascular accident: 1994, left carotid endarterectomy
- Bilateral inguinal herniorrhaphy: 1964
- Mild dementia
- Polycythemia vera
- Does not smoke or drink
- Previous bleed in 1994 after colon resection and NSAID use

P  
-  
U  
-  
W  
O  
L  
O  
T  
L  
O  
F



990616-SK909  
CELEBREX

Individual Safety Report



For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved under the authority of the Federal Acquisition Regulation (48 CFR 101-11.6)

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

CDEF

Form Use Only	112029
Change and instructions	

**A. Patient information**

1. Patient identifier: 157486  
In confidence

2. Age at time of event: 87  
Date of birth:

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kg

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcome attributed to adverse event (check all that apply):  
 death (immediate)  life-threatening  hospitalization - initial or prolonged  
 disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other:

3. Date of event (month/year): 10-26 99

4. Date of this report (month/year): 11-12-99

5. Describe event or problem:  
 Pt. presented to Dr. office with melena. Pt. sent to ER. Pt. Had been taking ADVIL 600mg pvn as new MD over weekend for foot pain. Admitted to hospital MD: suspect bleeding 2' to Antrol ulcer ADVIL. tx: prevacid 30mg BID

6. Relevant tests/laboratory data, including dates:  
 DCC  
 NOV 15 1999

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.):  
 Carcinosis with ascites  
 Variceal bleed  
 UGI bleed  
 Antrol ulcers

**C. Suspect medication(s)**

1. Name (give labeled strength & route/dose, if known):  
 #1 ADVIL 200mg  
 #2 ADVIL

2. Dose, frequency & route used:  
 #1 600mg pvn  
 #2

3. Therapy dates (if unknown, give duration) (month or last attempt):  
 #1 2 days  
 #2

4. Diagnosis for use (indication):  
 #1  
 #2

5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known): #1 #2

7. Exp. date (if known): #1 #2

8. Event reappeared after readministration:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only):

10. Concomitant medical products and therapy dates (exclude treatment of event):  
 CASIX  
 albuterol  
 INDERAL  
 calcium/jvit  
 Colace

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device:  
 health professional  
 lay user/patient  
 other:

5. Expiration date (month/year)

6. Device # REC'D

7. If implanted, give date (month/year)

8. If implanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on: (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter information**

1. Name (print name): RPH Director  
 Center Pharmacy  
 Ad-  
 [Redacted]

2. Health professional?  yes  no

3. Occupation: Pharmacist

4. Also reported to:  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, please an "X" in this box.



Mail to: MEDWATCH  
 6805 Fishers Lane  
 Rockville, MD 20852-0787

OR FAX to:  
 1-800-FDA-0178

FDA Form 3500 (10/99) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

NOV 12 '99 PM 1:21





VOLUNTARY reporting health professionals of adverse events and product problems  
CDER

Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse

FDA Use Only

Triage unit sequence # 113491

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_ of \_\_\_

CDER

A. Patient information

1. Patient Identifier 7086-04  
2. Age at time of event: 80.5  
3. Sex: [x] female [ ] male  
4. Weight: 105.1 lbs or \_\_\_ kgs

B. Adverse event or product problem

1. [x] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)  
2. Outcomes attributed to adverse event (check all that apply):  
[ ] death (mo/day/yr)  
[ ] life-threatening  
[x] hospitalization - initial or prolonged  
[ ] disability  
[ ] congenital anomaly  
[ ] required intervention to prevent permanent impairment/damage  
[ ] other:  
3. Date of event (mo/day/yr) 05/05/99  
4. Date of this report (mo/day/yr) 11/3/99

5. Describe event or problem  
GI bleeding  
microcytic anemia  
  
DSS  
NOV 30 1999  
ADVERSE EVENT REPORTING SYSTEM

6. Relevant tests/laboratory data, including dates  
Admission  
Hct (13.2), Hgb (4.1), RBC (1.95)  
WBC (10.2), MCV (68), MCH (21.1)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
  
CTU 113491

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)  
#1 ~~Adril~~ Adril  
#2  
2. Dose, frequency & route used  
#1  
#2  
3. Therapy dates (if unknown, give duration) from/to (or best estimate)  
#1  
#2  
4. Diagnosis for use (indication)  
#1  
#2  
5. Event abated after use stopped or dose reduced  
#1 [x] yes [ ] no [ ] doesn't apply  
#2 [ ] yes [ ] no [ ] doesn't apply  
6. Lot # (if known)  
#1  
#2  
7. Exp. date (if known)  
#1  
#2  
8. Event reappeared after reintroduction  
#1 [ ] yes [ ] no [x] doesn't apply  
#2 [ ] yes [ ] no [ ] doesn't apply  
9. NDC # (for product problems only)  
#1  
#2  
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name  
2. Type of device  
3. Manufacturer name & address  
4. Operator of device  
[ ] health professional  
[ ] lay user/patient  
[ ] other:  
5. Expiration date (mo/day/yr)  
6. model #  
catalog # NOV 30 1999  
serial #  
lot # MEDWATCH CTU  
other #  
7. If implanted, give date (mo/day/yr)  
8. If explanted, give date (mo/day/yr)  
9. Device available for evaluation? (Do not send to FDA)  
[ ] yes [ ] no [ ] returned to manufacturer on (mo/day/yr)  
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #  
MS, 12th  
Medical Center  
2. Health professional? [x] yes [ ] no  
3. Occupation Pharmacist  
4. Also reported to  
[ ] manufacturer  
[ ] user facility  
[ ] distributor  
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [x]



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787  
or FAX to: 1-800-FDA-0178

Individual Safety Report

health professionals of adverse events and product problems

CDEF

FDA Use Only

Telego unit sequence #

119699



Page \_\_\_ of \_\_\_

CDEF

A. Patient Information

1. Patient Identifier 75-43-93 In confidence	2. Age at time of event: 37 or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 134.9 lbs or kgs
--	--	---	-------------------------------------

B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (m/d/yyyy) 08/17/99

4. Date of this report (m/d/yyyy) 11/29/99

5. Describe event or problem

- Gastric ulcer scar  
- upper GI bleeding  
- Anemia

6. Relevant tests/laboratory data, including dates

Stomach pain, black bloody stool, gastroscopy showed gastric ulcer, upper GI bleeding secondary to gastric ulcer, WBC (10), Hgb (6.2), Hct (13.4), RBC (2.34), platelet (393).

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Rib fracture

OTU 119699

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Advil

#2 Naprosyn

2. Dose, frequency & route used

#1 BID to TID prn

#2 4-5 times daily prn

3. Therapy dates (if unknown, give duration) (month for best estimate)

4. Diagnosis for use (indication)

#1 pain

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS

DEC 03 1999

REC'D

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (m/d/yyyy)

6. If implanted, give date (m/d/yyyy)

7. If explanted, give date (m/d/yyyy)

8. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on (m/d/yyyy)

9. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone

[redacted] MS, RPH  
Medtronic Center

2. Health professional?  yes  no

3. Occupation Pharmacist

4. Also reported to

manufacturer

user facility

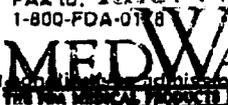
distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to: REC'D  
1-800-FDA-0118



Submission of a report does not constitute an admission of liability by the reporter, the manufacturer, or the product caused or contributed to the event.

DEC 2 '99 AM 11:31



\*3413006-6-00-01\*

For use by user-facilities,  
butors and manufacturers for  
**MANDATORY** reporting

Mfr report #	99-0160-024	( 99-3986 )
UF/Dist report #		
FDA Use Only		

Page 1 of 1

**A. Patient information**

1. Patient identifier [redacted]	2. Age at time of event: 80 or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 200 lbs or -NI kgs
-------------------------------------	--	---	---------------------------------------

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event: 09/99

4. Date of this report: 11/24/99

5. Describe event or problem

An 80 year old male consumer reported that he experienced chills after 6 months of dosing tid with the doctor-recommended product for arthritic pain in the wrist. After seeing doctors due to the symptom, he was hospitalized on 10/15. A colonoscopy exam determined the diagnoses of bleeding ulcer, hiatal hernia and diverticulitis. He was informed by the doctors that "he was bleeding from 3 different locations caused by Advil overdose." He reported that while hospitalized he had to have 2 blood transfusions due to low red blood cell count. At the time of call he stated that he was discharged 11 days later, the product was discontinued and is currently being treated aggressively with medication, the names of which he did not recall. Medical records have been requested. No further symptoms or sequelae reported.

6. Relevant tests/laboratory data, including dates

Colonoscopy

DEC 02 1999

Allergy history unknown.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Med Cond: Arthritis & Hx of prostate cancer  
Surgery: Lymph node surgery 10/99  
First time use of product.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)		
#1	Advil (R) (Ibuprofen) Caplets	
#2	-NA	
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from to (or best estimate)
#1	2 tabs po tid po	#1 6 month(s)
#2	-NA	#2
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced
#1	Arthritis	#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	-NA	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)	
#1 91G68	#1 02/01	
#2 -NA	#2 -NA	
9. NDC # - for product problems only (if known)		
0573 - 0160 -		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
Multivitamins Medications (does not recall)		

**D. Suspect medical device**

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional <input type="checkbox"/> lay user: patient <input type="checkbox"/> other
6. model #	5. Expiration date (mo day yr)
catalog # DEC 03 1999	
serial #	7. If implanted, give date (mo day yr)
lot #	8. If explanted, give date (mo day yr)
other #	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo day yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**E. Initial reporter**

1. Name, address & phone #		
Mr. [redacted] United St		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	-NA	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

pm 11. 24. 99



\*3413006-6-00-02\*

Content of a report does not constitute  
 on that medical personnel, user  
 distributor, manufacturer or product  
 involved or contributed to the event.

Page \_\_\_ of \_\_\_

FDA Use Only

### F. For use by user facility/distributor—devices only

1. Check one <input checked="" type="checkbox"/> user facility <input type="checkbox"/> distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (mo/day/yr)		7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	8. Date of this report (mo/day/yr)
9. Approximate age of device	10. Event problem codes (refer to coding manual) patient code: [ ] - [ ] - [ ] device code: [ ] - [ ] - [ ]		
11. Report sent to FDA? <input type="checkbox"/> yes (mo/day/yr) _____ <input type="checkbox"/> no		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> other: _____ specify	
13. Report sent to manufacturer? <input type="checkbox"/> yes (mo/day/yr) _____ <input type="checkbox"/> no		14. Manufacturer name/address	

DEC 02 1999

### G. All manufacturers

1. Contact office - name/address (& mfgng site for devices)		2. Phone number	
Whitehall-Robins Medical Department 5 Giralda Farms Madison, NJ                      07940-0871		973-660-5500	
4. Date received by manufacturer (mo/day/yr) 10/18/99		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other	
5. (A)NDA # 18-989 IND # -NA PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes		8. Adverse event term(s) ULCER STOMACH HEM COLITIS HERNIA CHILLS	
6. If IND, protocol #		9. Mfr. report number	
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		99-0160-024	

### H. Device manufacturers only

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guidelines) <input type="checkbox"/> other: _____	2. If follow-up, what type? <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation
3. Device evaluated by mfr? <input type="checkbox"/> not returned to mfr. <input type="checkbox"/> yes <input type="checkbox"/> evaluation summary attached <input type="checkbox"/> no (attach page to explain why not) or provide code: _____	4. Device manufacture date (mo/yr)
5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no	
6. Evaluation codes (refer to coding manual) method: [ ] - [ ] - [ ] - [ ] results: [ ] - [ ] - [ ] - [ ] conclusions: [ ] - [ ] - [ ] - [ ]	
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> patient monitoring <input type="checkbox"/> relabeling <input type="checkbox"/> modification/adjustment <input type="checkbox"/> other: _____	8. Usage of device <input type="checkbox"/> initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown
9. If action reported to FDA under 21 USC 360(i)(f), list correction/removal reporting number:	

10. <input type="checkbox"/> Additional manufacturer narrative	and/or	11. <input type="checkbox"/> Corrected data
--	--------	---

DSS  
DEC 03 1999

The public reporting burden for this collection of information has been estimated to average one-hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
 Hubert H. Humphrey Building, Room 721-B  
 200 Independence Avenue, S.W.  
 Washington, DC 20201  
 ATTN: FRA

and to:  
 Office of Management and Budget  
 Paperwork Reduction Project (0910-0291)  
 Washington, DC 20503

Please do NOT return this form to either of these addresses.



VOLUNTARY reporting health professionals of adverse events and product problems

CDER

Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse

FDA Use Only

Triage unit sequence # 113913

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

CDER

A. Patient information

1. Patient identifier [redacted] 2. Age at time of event: 56 or Date of birth: 3. Sex: [ ] female [x] male 4. Weight: 100 lbs or kgs

B. Adverse event or product problem

1. [ ] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions) 2. Outcomes attributed to adverse event (check all that apply) [ ] death [ ] life-threatening [ ] hospitalization - initial or prolonged [ ] disability [ ] congenital anomaly [x] required intervention to prevent permanent impairment/damage [ ] other: 3. Date of event (mo/day/yr) 7/10/99 4. Date of this report (mo/day/yr) 11/29/99

5. Describe event or problem: CT bleeding, melena, syncope, gastric ulcer, 2° Advil (ibuprofen) 3000 mg po per day - 1 yr for pain (prior to Advil) BI cap cautery, Pepcid 20mg IV bid x 2 days then Prilosec 20mg po BID

6. Relevant tests/laboratory data, including dates: 1 cm peptic ulcer

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) DSS DEC 10 1999 ADVERSE EVENT REPORTING SYSTEM

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 Advil #2 2. Dose, frequency & route used #1 3000mg/day #2 3. Therapy dates (if unknown, give duration) #1 x/yr PTA #2 4. Diagnosis for use (indication) #1 Pain #2 5. Event abated after use stopped or dose reduced #1 [x] yes [ ] no [ ] doesn't apply #2 [ ] yes [ ] no [x] doesn't apply 6. Lot # (if known) #1 #2 7. Exp. date (if known) #1 #2 8. Event reappeared after reintroduction #1 [ ] yes [ ] no [ ] doesn't apply #2 [ ] yes [ ] no [ ] doesn't apply 9. NDC # (for product problems only) #1 #2 10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name 2. Type of device 3. Manufacturer name & address 4. Operator of device [ ] health professional [ ] lay user/patient [ ] other: 5. Expiration date (mo/day/yr) 6. model # REC'D. catalog # DEC 09 1999 serial # MEDWATCH CTU lot # other # 7. If implanted, give date (mo/day/yr) 8. If explanted, give date (mo/day/yr) 9. Device available for evaluation? (Do not send to FDA) [ ] yes [ ] no [ ] returned to manufacturer on (mo/day/yr) 10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone # [redacted] Pharm.D. [redacted] HOSPITAL [redacted] 2. Health professional? [x] yes [ ] no 3. Occupation: Clinical RN 4. Also reported to [ ] manufacturer [ ] user facility [ ] distributor 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [x]



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178



\*3432103-2-00-01\*

Use by user-facilities, distributors and manufacturers for MANDATORY reporting

Form Approved OMB No. 0910-0291 Expires 12/31/94 See OMB statement on reverse

Mfr report #	98-0169-038	( 98-2842 )
UF/Dial report #		
FDA Use Only		

Page 1 of 1

<b>A. Patient information</b>			
1 Patient identifier	2 Age at time of event: 52 Date of birth: -NI	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 92 lbs -NI kgs
<b>B. Adverse event or product problem</b>			
1 <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2 Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other			
3 Date of event 10/1998	4 Date of this report 12/10/98		
5 Describe event or problem			
<p>A 52-year-old female reported that she used 2 Advil liqui-gels to relieve fever. Three days later she took another 2 liqui-gels and some-time later that day noticed blood on the tissue after having a bowel movement. The following day she noticed traces of blood in her stool. She also experienced some stomach tenderness. The bleeding abated after 2 days. At the time of reporting, about 1 week after the last dose, she still feels some tenderness in her stomach. The consumer was referred to a physician. No further symptoms or sequelae were reported.</p>			
c Relevant tests/laboratory data including dates			
No information provided.			
Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
No additional medical history information provided			
No allergy history reported.			

<b>C. Suspect medication(s)</b>			
1 Name (give labeled strength & mfr/labeler, if known)			
#1 Advil (R) (Ibuprofen) Liqui-Gels			
#2 -NA			
2 Dose, frequency & route used		3 Therapy dates (if unknown, give duration, from to or best estimate)	
#1 2 liqui-gels prn		#1 2	
#2 -NA		#2	
4 Diagnosis for use (indication)			5 Event abated after use stopped or dose reduced
#1 cold and fever			#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 -NA			#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6 Lot # (if known)	7 Exp. date (if known)		8 Event reappeared after reintroduction
#1 Unknown	#1 -NA		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 -NA	#2 -NA		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9 NDC # - for product problems only (if known) 0573 - 0169 -			
10 Concomitant medical products and therapy dates (exclude treatment of event) None reported.			

<b>D. Suspect medical device</b>			
1 Brand name			
2 Type of device			
3 Manufacturer name & address			4 Operator of device
			<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
6 model #			5 Expiration date
catalog #			7 If implanted, give date
serial #			8 If explanted, give date
lot #			
other #			
9 Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____			
10 Concomitant medical products and therapy dates (exclude treatment of event)			

<b>E. Initial reporter</b>			
Name, address & phone #			
Ms. [redacted] St. [redacted] United States			
MAR 1 - 1999			
By [redacted]			

2 Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3 Occupation -NA	4 Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unknown
---	---------------------	--



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

P.F. 12/10/98

00-0013



\*3432103-2-00-02\*

of a report does not constitute that medical personnel, user, manufacturer or product contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service - Food and Drug Administration

Page of

FDA Use

**F. For use by user facility/distributor—devices only**

1 Check one  
 user facility  distributor

2 UF/Dist report number

3 User facility or distributor name/address

4 Contact person

5 Phone Number

6 Date user facility or distributor became aware of event (mo/day/yr)

7 Type of report  
 initial  
 follow-up # \_\_\_\_\_

8 Date of this report (mo/day/yr)

9 Approximate age of device

10 Event problem codes (refer to coding manual):  
 patient code: [ ] - [ ] - [ ]  
 device code: [ ] - [ ] - [ ]

11 Report sent to FDA?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

12 Location where event occurred  
 hospital  outpatient diagnostic facility  
 home  ambulatory surgical facility  
 nursing home  
 outpatient treatment facility  
 other \_\_\_\_\_

13 Report sent to manufacturer?  
 yes (mo/day/yr) \_\_\_\_\_  
 no

14 Manufacturer name/address

**G. All manufacturers**

1 Contact office - name/address (& mailing site for devices)

2 Phone number

3 Report source (check all that apply):  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other \_\_\_\_\_

4 Date received by manufacturer (mo/day/yr)

5 (A)INDA # 20-402  
 IND # -NA  
 PLA #  
 pre-193P  yes  
 OTC product  yes

6 Adverse event term(s)  
 HEM GI  
 HEM RECTAL  
 PAIN ABDO

7 Type of report (check all that apply):  
 5-day  15-day  
 10-day  periodic  
 initial  follow-up # \_\_\_\_\_

8 Mfr. report number

**H. Device manufacturers only**

1 Type of reportable event  
 death  
 serious injury  
 malfunction (see guidelines)  
 other \_\_\_\_\_

2 If follow-up, what type?  
 correction  
 additional information  
 response to FDA request  
 device evaluation

3 Device evaluated by mfr?  
 not returned to mfr  
 yes  evaluation summary attached  
 no (attach page to explain why not) or provide code \_\_\_\_\_

4 Device manufacture date (mo/day/yr)

5 Labeled for single use?  
 yes  no

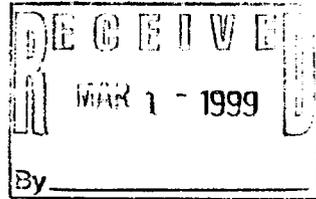
6 Evaluation codes (refer to coding manual):  
 method: [ ] - [ ] - [ ] - [ ]  
 results: [ ] - [ ] - [ ] - [ ]  
 conclusions: [ ] - [ ] - [ ] - [ ]

7 If remedial action initiated, check type:  
 recall  notification  
 repair  inspection  
 replace  patient monitoring  
 relabeling  modification/adjustment  
 other \_\_\_\_\_

8 Usage of device  
 initial use of device  
 reuse  
 unknown

9 If action reported to FDA under 21 USC 360(f), list correction/removal reporting number

10  Additional manufacturer narrative and/or 11  Corrected data



The public reporting burden for this collection of information has been estimated to average one hour per response... Please do NOT return this form to either of these addresses.



use by user-facilities,
ors and manufacturers for
Mandatory reporting

See OMB statement on reverse
Mfr report # 98-0169-040 (98-2844)
UP/Dist report #
FDA Use Only

A. Patient information

1 Identifier
2 Age at time of event: 58
3 Sex female
4 Weight 125 lbs

B. Adverse event or product problem

1 Adverse event and/or Product problem

2 Outcomes attributed to adverse event
death
life-threatening
hospitalization
disability
congenital anomaly
required intervention to prevent permanent impairment/damage
other

3 Date of event
4 Date of this report 12/10/98

5 Describe event or problem
A reporter stated that her 58-year-old friend used Advil liqui-gels, 2 liqui-gels daily to relieve fever and on the 2nd day experienced rectal spotting. (The consumer is postmenopausal.) She discontinued the product and the event abated. The consumer was referred to a physician. No further symptoms or sequelae were reported.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1 Advil (R) (Ibuprofen) Liqui-Gels

2 Dose, frequency & route used
#1 2 liqui-gels daily

3 Therapy dates
#1 2 day(s)

4 Diagnosis for use (indication)
#1 fever

5 Event abated after use stopped or dose reduced
#1 yes

6 Lot # (if known)
#1 Unknown

7 Exp. date (if known)
#1 -NA

8 Event reappeared after reintroduction
#1 no

9 NDC # - for product problems only (if known)
0573 - 0169

10 Concomitant medical products and therapy dates (exclude treatment of event)
Prozac (fluoxetine)

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device
health professional
lay user/patient
other

5 Expiration date

6 model #
catalog #
serial #
lot #
other #

7 If implanted, give date
8 If explanted, give date

9 Device available for evaluation?
yes no returned to manufacturer on

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1 Name, address & phone #
Ms.
St.
United States



2 Health professional?
yes no

3 Occupation
-NA

4 Initial reporter also sent report to FDA
yes no unknown



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

12/10/98

00-0014



\*3432168-1-00-02\*

if a report does not constitute that medical personnel, user, manufacturer or product contributed to the event.

Page of

FDA Use

F. For use by user facility/distributor—devices only

Form F containing sections 1-14 for user facility/distributor use, including fields for report number, name/address, contact person, phone number, date of event, type of report, and location.

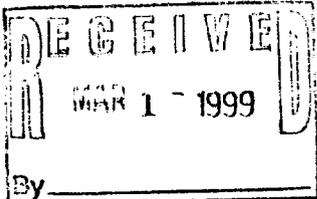
G. All manufacturers

Form G containing sections 1-6 for all manufacturers, including fields for contact office, phone number, report source, date received, and adverse event terms.

H. Device manufacturers only

Form H containing sections 1-9 for device manufacturers, including fields for type of reportable event, follow-up type, device evaluation, and remedial action.

Form H continuation containing sections 10-11 for additional manufacturer narrative and corrected data.



The public reporting burden for this collection of information has been estimated to average one hour per response...

Reports Clearance Office: PHS, Hubert H. Humphrey Building, Room 721 B, Washington, DC 20201

and to Office of Management and Budget, Paperwork Reduction Project (0910-0291), Washington, DC 20503

Please do NOT return this form to either of these addresses.



For VOLUNTARY reporting  
by health professionals of adverse  
events and product problems

Form Approved 248 No. 10-201 Expires 10-94  
See 248 Statement for Details

FOIA Use Only

Trace unit  
sequence # **116137**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page

CDER

CDER

**A. Patient information**

1. Patient identifier: [redacted] In confidence

2. Age at time of event: \_\_\_\_\_ or Date of birth: \_\_\_\_\_

3. Sex:  female or  male

4. Weight: \_\_\_\_\_ lb or \_\_\_\_\_ kg

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):  
 death  
 life-threatening  
 hospitalization -  initial or  prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 Other: **Severe**

3. Date of event (month/year): **4/19/99**

4. Date of this report (month/year): **12/16/99**

5. Describe event or problem:  
**Nausea + ↑ stool frequency**  
**→ 2 episodes dark + Tarry Stools**  
**Syncope episodes**  
**→ coffee-ground emesis + 3-4**  
  
**Tx: 2L NSS, pepid, 10pRBC**  
**→ pepid + prevacid started**

6. Relevant tests/laboratory data, including dates:  
**H. pylori ⊖**  
**GI consult: gastric ulcer D2.**  

H/H - 4/19	20	21
9.17/27	4.2/27	4.7/27

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.):  
**CHRONIC POTATOY CUTI FEV**

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeled, if known):  
 #1 **ADVICIL**  
 #2 **ANACIN**

2. Dose, frequency & route used:  
 #1 **200mg Q6 PO**  
 #2 **2 tabs Qweek PO**

3. Therapy dates (if unknown give duration) (month/year for best estimate):  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

4. Diagnosis for use (indication):  
 #1 **Potatoy cuti fev**  
 #2 **Leision**

5. Event abated after use stopped or dose reduced:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

6. Lot # (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

7. Exp. date (if known): #1 \_\_\_\_\_ #2 \_\_\_\_\_

8. Event reappeared after reintroduction:  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only): #1 \_\_\_\_\_ #2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event):

**D. Suspect medical device**

1. Brand name: \_\_\_\_\_

2. Type of device: \_\_\_\_\_

3. Manufacturer name & address:  
**DSS**  
**FEB 02 2000**

4. Operator of device:  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (month/year): \_\_\_\_\_

6. Model #: **REC'D.**

7. If implanted, give date (month/year): \_\_\_\_\_

8. If explanted, give date (month/year): \_\_\_\_\_

9. Catalog #: \_\_\_\_\_

10. Serial #: **FEB 02 2000**

11. Lot #: \_\_\_\_\_

12. Other #: **MEDWATCH CTU**

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event):

**E. Reporter**

1. Name, address:  
 [redacted] MS, RPh  
 [redacted] Hospital Pharmacy  
 [redacted] Ave

2. Health professional?  yes  no

3. Occupation: **RPh**

4. Also reported to:  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
or FAX to:  
1-800-FDA-0178

FOIA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 116137



\*3451209-5-00-01\*

of event: 72  female  male  Weight      lbs or      kgs

Date of birth:     

In confidence

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death  disability  congenital anomaly

life-threatening (mortality)  required intervention to prevent permanent impairment/damage

hospitalization - initial or prolonged  other:     

3. Date of event (m/d/yyyy) 11/3/99 4. Date of this report (m/d/yyyy) 2/2/00

5. Describe event or problem

Patient takes aduic and celebrex for the treatment of pain in his knees and headaches. Patient was admitted for upper GI bleeds and possible toxic metabolic encephalopathy.

6. Relevant tests/laboratory data, including dates

**REC'D.**  
**FEB 03 2000**  
**MEDWATCH CTU**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 aduic

#2 Celebrex

2. Dose, frequency & route used

#1     

#2     

3. Therapy dates (if unknown, give duration)

#1     

#2     

4. Diagnosis for use (indication)

#1 pain and headache

#2     

5. Event abated after use

stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1     

#2     

7. Exp. date (if known)

#1     

#2     

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

**DSS**  
**FEB 03 2000**

4. Operator of device

health professional

lay user/patient

other:     

5. Expiration date (m/d/yyyy)

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on      (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

     M.S., Pharm.D.

     M.S., Pharm.D.

**E. Reporter (see confidentiality section on back)**

1. Name & address

     Medical Center

Att: Pharmacy Department

2. Health professional?  yes  no

3. Occupation

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

PLEASE TYPE OR USE BLACK INK

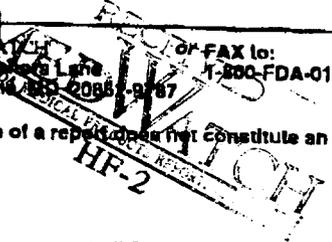


Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20857-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (7/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event



CTU 116328

FEB 3 '00 AM 9:28



OLUNTARY reporting  
lth professionals of adverse  
nts and product problems

OVER  
COE

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse

FDA Use Only H Pad  
Triage unit sequence # 117402

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_ of \_\_\_

**A. Patient information**

1. Patient identifier #6054  
2. Age at time of event: 95  
3. Sex  female  male  
4. Weight 94 lbs or \_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)  
2. Outcomes attributed to adverse event (check all that apply):  
 death (mo/day/yr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (mo/day/yr) 12-2-98  
4. Date of this report (mo/day/yr) 3-10-00

5. Describe event or problem  
95 yo F admitted after episode of syncope and loss of consciousness with bradycardia (HR 40-50's). The patient was admitted to intensive care with severe anemia, (qibl&d) hypotension and dehydration, hyperkalemia and digoxin toxicity. (EK G shows sinus bradycardia (49), first degree AV block, short QT interval and anterolateral ST-T abnormalities. (dig level = 2.79); temp = 96.2, R = 22, HR 40-50, BP 118/31  
12/2 12/4  
dig 2.79 1.1

6. Relevant tests/laboratory data, including dates

	12/2	12/3	12/4	12/6
hem	4.4	8.1	10.7	Endo shows multiple gastric ulcers & erosions
HCT	14	25	33.2	
Cr	1.3	1.6	0.9	
BUN	45	46	29	
K	7.1	5.3	3.5	
PT	20.6		12.4	
INR	3.1		1.1	

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
no drug allergies, no ETOH, no tobacco  
Hx of chronic atrial fib, CHF, hypertensive cardiovascular dz, osteoporosis, anemia

CTU 117402

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
#1 Celebrex T.MOTRIN (COE) daily  
#2 Coumadin ~ 11/30/99  
2. Dose, frequency & route used  
#1 200mg qd x 2 wks  
#2 4mg po qd  
3. Therapy dates (if unknown, give duration) from/no (or best estimate)  
#1 11/30/99 - 12/2/99  
#2 12/2/99  
4. Diagnosis for use (indication)  
#1 Arthritis  
#2 Atrial Fib  
5. Event abated after use stopped or dose reduced  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply  
6. Lot # (if known) #1 ? #2 ?  
7. Exp. date (if known) #1 #2  
8. Event reappeared after reintroduction  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply  
9. NDC # (for product problems only)  
10. Concomitant medical products and therapy dates (exclude treatment of event)  
Tylenol Ext. St. 500mg qd Lanoxin 0.125mg qd  
Tenormin 25 po qd MVI po qd  
Lasix 60mg qd Robaxin 500mg po bid  
K-Dur 20mg qd Vicodin 796 prn

**D. Suspect medical device**

1. Brand name  
2. Type of device DSS  
3. Manufacturer name & address FEB 18 2000  
4. Operator of device  health professional  lay user/patient  other:  
5. Expiration date (mo/day/yr)  
6. model # FEB 18 2000  
7. If implanted, give date (mo/day/yr)  
8. If explanted, give date (mo/day/yr)  
9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on (mo/day/yr)  
10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #  
Dept of Pharmacy  
Hospital  
Rd.  
2. Health professional?  yes  no  
3. Occupation Pharmacist  
4. Also reported to  manufacturer  user facility  distributor  
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mall to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787  
or FAX to: 1-800-FDA-0178



\*3464529-5-00-01\*

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting CDER  
by health professionals of adverse  
events and product problems

Form Approved DMB No. 2813-129 Expires 2/31/00  
See DMB Statement on Reverse

FDA Use Only

Trace unit sequence # **117866**

Page \_\_\_ of \_\_\_

CDER

**A Patient information**

1. Patient identifier **[redacted]** 2. Age at time of event: 92 or Date of birth: [redacted] 3. Sex  female  male 4. Weight 66 lbs or 66 kgs

**B Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death  life-threatening  Hospitalization  initial  prolonged  disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other: Severe

3. Date of event (mandatory) 10/12/99 4. Date of this report (mandatory) 2/1/00

5. Describe event or problem

2 day hx/o weakness & falling  
2 week hx/o melanic stools

Tx: had NSAIDs

6. Relevant tests/laboratory data, including dates

↓ Hct = 13

**DSS**  
**FEB 29 2000**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Chronic NSAID use

CTU 117866

**C Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 Aspirin ASPIRIN  
#2 Advil ADVIL

2. Dose, frequency & route used

#1 325mg PO QD  
#2 300mg PO QD

3. Therapy dates (if unknown give duration) (month or best estimate)

#1 [redacted]  
#2 [redacted]

4. Diagnosis for use (indication)

#1 CHF - Afib  
#2 Chronic back pain

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

6. Lot # (if known) #1 [redacted] #2 [redacted]

7. Exp. date (if known) #1 [redacted] #2 [redacted]

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 [redacted] #2 [redacted]

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (mandatory)

6. model # RECEIVED  
catalog # FEB 29 2000  
serial # MEDWATCH CTU

7. If implanted, give date (mandatory)

8. If explanted, give date (mandatory)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on [redacted] (mandatory)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E Reporter**

1. Name, address & phone

[redacted], MS, RPh  
Department of Pharmacy  
[redacted] Hospital  
[redacted] Ave

2. Health professional?  Yes  No 3. Occupation RPh

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

**FDA** Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-0787

or FAX to:  
1-800-FDA-0178



\*3476797-6-00-01\*

**VOLUNTARY reporting**  
 health professionals of adverse  
 events and product problems

FDA Use Only

Triage unit  
 sequence # **118454**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page **CDEB**

**CDEB**

**A. Patient information**

1. Patient identifier <b>9083</b> In confidence	2. Age at time of event: or <b>59</b> Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	--	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yr) <b>11-29-99</b>	4. Date of this report (m/d/yr)
---	---------------------------------

5. Describe event or problem

**GI BLEED  
 ↳  
 HEMATEMESIS**

**TAKING OTC IBUPROFEN  
 AS WELL AS RX NAPROXEN**

6. Relevant tests/laboratory data, including dates

**DSS**

**MAR - 8 2000**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeled, if known)		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1 <b>IBUPROFEN</b>		#1 <b>N/A</b>	
#2 <b>NAPROXEN</b>		#2 <b>10-98</b>	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 <b>OTC</b>		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <b>375mg BID</b>		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 <b>ARTHRITIS</b>		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	9. NDC # (for product problems only)	
#1	#1		
#2	#2		

10. Concomitant medical products and therapy dates (exclude treatment of event)

**ALBUTEROL ATIVAN  
 VERAPAMIL LISINAPRIL  
 FLEXERIL ATROVENT**

**D. Suspect medical device**

1. Brand name		4. Operator of device	
		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:	
2. Type of device		5. Expiration date (m/d/yr)	
3. Manufacturer name & address		7. If implanted, give date (m/d/yr)	
6. model #		8. If explanted, give date (m/d/yr)	
catalog # <b>MAR 08 2000</b>			
serial # <b>MEDWATCH CTU</b>			
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (m/d/yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #			
<b>OVERTON BROOKS VA MEDICAL CENTER          510 EAST STONER AVENUE          SHREVEPORT, LOUISIANA 71101-4295          (318)-424-6001</b>			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation <b>RPH</b>	4. Also reported to	
		<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			

**CTU118454**



Mail to: **MEDWATCH**  
 5600 Fishers Lane  
 Rockville, MD 20852-9787

or FAX to:  
 1-800-FDA-0178



**VOLUNTARY** reporting  
health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/04  
See OMB statement on reverse

FDA Use Only	
Triage unit sequence #	118472

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page CDER of CDER

A. Patient information			
1. Patient identifier 60293 In confidence	2. Age at time of event: 46 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> life-threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage		
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> other: _____		
3. Date of event (mo/day/yr) 10-16-99	4. Date of this report (mo/day/yr)		
5. Describe event or problem			
COFFEE GROUND EMESIS BLACK TARRY STOOL			
6. Relevant tests/laboratory data, including dates			
DSS MAR - 8 2000			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
ETOH ABUSE			
CTU 118472			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 IBUPROFEN			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1 OTC		#1 ?	
#2		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 PAIN		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply			
9. NDC # (for product problems only)			
-			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
ALBUTEROL    LANSOPRAZOLE ALLOPURINOL NIFEDIPINE			

D. Suspect medical device	
1. Brand name	
2. Type of device	
3. Manufacturer name & address	
RECEIVED	
model # _____	
catalog # MAR 08 2000	
serial # MEDWATCH CTU	
lot # _____	
other # _____	
4. Operator of device	
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other: _____	
5. Expiration date (mo/day/yr)	
6. If implanted, give date (mo/day/yr)	
7. If explanted, give date (mo/day/yr)	
8. If explanted, give date (mo/day/yr)	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)			
1. Name, address & phone #			
OVERTON BROOKS VA MEDICAL CENTER 510 EAST STONER AVENUE SHREVEPORT, LOUISIANA 71101-4295 (318)-424-6001			
2. Health professional?	3. Occupation	4. Also reported to	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	RPL	<input type="checkbox"/> manufacturer	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.		<input type="checkbox"/> user facility	
<input checked="" type="checkbox"/>		<input type="checkbox"/> distributor	



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
or FAX to:  
1-800-FDA-0178



VOLUNTARY reporting  
with professionals of adverse  
events and product problems

June/July 1999

Form Approved: OMB No. 0910-0291 Expires 12/31/94  
See OMB statement on rev. 1/94

FDA Use Only

Triage unit sequence # 120177  
CDER

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of CDER

**A. Patient information**

1. Patient identifier: 2415  
2. Age at time of event: 49  
3. Sex:  male  
4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)  
2. Outcomes attributed to adverse event (check all that apply):  
 death (mo/day/yr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: GI bleed  
3. Date of event (mo/day/yr): 6/1/99  
4. Date of this report (mo/day/yr): 6/2/99

5. Describe event or problem  
Pt admitted from ED after 40 hemoptysis <sup>x5 episodes</sup> / dizziness, fever & chills since the night before. Pt admitted for GI bleed 2° to W/O Du PUD since '74, GERD, + HTN. Pt reports using 12 Ibuprofen w/in the past week. Also had used aspirin. GI scope shows Mallory-Weiss tears. Pt sedated + no written history or computer Rx's for doses/strengths/ of ASA + IBU.

6. Relevant tests/laboratory data, including dates  
NKDA Home @ stool  
W/O EtOH abuse @ melena  
Hct - 32.6  
Hgb - 10

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTU 120177

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787  
or FAX to: 1-800-FDA-0178

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
#1: IBU - OTC IBUPROFEN  
#2: ASA - OTC  
2. Dose, frequency & route used:  
#1: 200mg prn  
#2: 325mg prn  
3. Therapy dates (if unknown, give duration) (mo/day/yr):  
#1: \_\_\_\_\_  
#2: \_\_\_\_\_  
4. Diagnosis for use (indication):  
#1: \_\_\_\_\_  
#2: \_\_\_\_\_  
5. Event abated after use stopped or dose reduced:  
#1:  yes  no  doesn't apply  
#2:  yes  no  doesn't apply  
6. Lot # (if known):  
#1: \_\_\_\_\_  
#2: \_\_\_\_\_  
7. Exp. date (if known):  
#1: \_\_\_\_\_  
#2: \_\_\_\_\_  
8. Event reappeared after reintroduction:  
#1:  yes  no  doesn't apply  
#2:  yes  no  doesn't apply  
9. NDC # (for product problems only):  
#1: \_\_\_\_\_  
#2: \_\_\_\_\_  
10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name: DSS  
2. Type of device: APR X 7 2000  
3. Manufacturer name & address: MEDWATCH CTU  
4. Operator of device:  
 health professional  
 lay user/patient  
 other:  
5. Expiration date (mo/day/yr):  
6. model #: RECEIVED  
7. If implanted, give date (mo/day/yr): APR 07 2000  
8. If explanted, give date (mo/day/yr): MEDWATCH CTU  
9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on (mo/day/yr):  
10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #:  
VAMC  
1030 Jefferson Ave  
Memphis, TN 38104  
2. Health professional?  yes  no Occupation: Pharm  
3. Also reported to:  
 manufacturer  
 user facility  
 distributor  
4. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



3486925-2-00-01

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Voluntary reporting by health professionals of adverse events and product problems

Internet Submission - Page 1

CDEF

Form Approved: OMB No. 0910-0281 Expires: 03/31/00 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

120498

### A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 45 Years or Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 213 lbs or ____ kgs
-------------------------------------	---	---	--

### B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	
3. Date of event (mm/dd/yyyy) 04/11/2000	4. Date of this report (mm/dd/yyyy) 04/11/2000

5. Describe event or problem

Patient was taking ibuprofen -purchased over the counter- 600mg three times daily for pain. He claimed he had arthritis in his back. He had taken this dose for about 5 consecutive days. While at work he complained of nausea and soon after vomited a large amount of bright red blood. He was admitted to [Redacted] Hospital and treated. He reported he took no other medications prior to admission.

6. Relevant tests/laboratory data, including dates

**RECEIVED**  
APR 12 2000  
**MEDWATCH CTU**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Arthritis of the back

### C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 ibuprofen / 200mg / unknown	
#2 / /	
2. Dose/Frequency/Route used	
#1 600mg / TID / Oral	
#2 / /	
3. Therapy dates (if unknown, give duration)	
#1 From 04/06/2000 To (or best estimate) 04/11/2000	
#2 -	
4. Diagnosis for use (separate indications with commas)	
#1 Arthritis of back	
#2	
5. Event abated after use stopped or dose reduced	
#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	
#1	
#2	
7. Exp. date (if known)	
#1	
#2	
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # (for product problems only)	
-	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

### D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	
<b>DSS</b> <b>APR 12 2000</b>	
4. Operator of device	
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other: _____	
5. Expiration date (mm/dd/yyyy)	
6. model # _____	
7. If implanted, give date (mm/dd/yyyy)	
8. If explanted, give date (mm/dd/yyyy)	
9. Device available for evaluation? (Do not send device to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

### E. Reporter (see confidentiality section on back)

1. Name		phone #
[Redacted], Pharm.D.		[Redacted]
[Redacted] Avenue		
United States		
2. Health professional?	3. Occupation	4. Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacist	<input type="checkbox"/> manufacturer
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		<input type="checkbox"/> user facility
		<input type="checkbox"/> distributor



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-0787  
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

HF-2



VOLUNTARY reporting  
Health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse  
FDA Use Only H Pad  
Triage unit sequence # **120782**

PRODUCTS REPORTING PROGRAM

Page **CDER**

*CDER*

**A. Patient information**

1. Patient identifier **910997**  
2. Age at time of event: **73**  
or Date of birth:  
3. Sex  female  male  
4. Weight \_\_\_ lbs or \_\_\_ kgs  
In confidence

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)  
2. Outcomes attributed to adverse event (check all that apply)  
 death (mo/day/yr)  disability  
 life-threatening  congenital anomaly  
 hospitalization - initial or prolonged  required intervention to prevent permanent impairment/damage  
 other:  
3. Date of event (mo/day/yr) **12/16/99**  
4. Date of this report (mo/day/yr) **4/4/00**

5. Describe event or problem  
*patient admitted with GI bleed as a dark stool. GI bleed diagnosis made. patient had been using ibuprofen 400mg OTC qd while @ home while on warfarin w/out knowledge of M.D. patient given vitamin K admit & transfused w/ PRBCs  
= ibuprofen OTC d*

6. Relevant tests/laboratory data, including dates  
*Admitting Hgb = 6.0*  
**DSS**  
**APR 18 2000**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
*Metastatic (Boney Dx) Breast Ca*  
**CTU 120782**

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
#1 **Ibuprofen**  
#2  
2. Dose, frequency & route used  
#1 **400mg qd OTC**  
#2  
3. Therapy dates (if unknown, give duration) (from to (or best estimate))  
#1 **PTA**  
#2  
4. Diagnosis for use (indication)  
#1 **Pain**  
#2  
5. Event abated after use stopped or dose reduced  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply  
6. Lot # (if known)  
#1  
#2  
7. Exp. date (if known)  
#1  
#2  
8. Event reappeared after reintroduction  
#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply  
9. NDC # (for product problems only)  
#1  
#2  
10. Concomitant medical products and therapy dates (exclude treatment of event)  
*Warfarin  
Paracet*

**D. Suspect medical device**

1. Brand name  
2. Type of device  
3. Manufacturer name & address  
4. Operator of device  
 health professional  
 lay user/patient  
 other:  
5. Expiration date (mo/day/yr)  
6. **RECEIVED**  
model #  
catalog # **APR 17 2000**  
serial # **MEDWATCH CTU**  
lot #  
other #  
7. If implanted, give date (mo/day/yr)  
8. If explanted, give date (mo/day/yr)  
9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on (mo/day/yr)  
10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone  
*Medical Center  
Pharmacy*  
2. Health professional?  yes  no  
3. Occupation **PPH**  
4. Also reported to  
 manufacturer  
 user facility  
 distributor  
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787  
or FAX to:  
1-800-FDA-0178



Voluntary reporting  
health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94  
See OMB statement on reverse

FDA Use Only (OMB):  
Triage unit sequence # WISSD  
CDEK

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_ of \_\_\_

CDEK  
MRU

**A. Patient information**

1. Patient identifier 169 2. Age at time of event: 64 3. Sex  female  male 4. Weight \_\_\_ lbs or \_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death (mortality)  disability  
 life-threatening  congenital anomaly  
 hospitalization - initial or prolonged  required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (m/d/yyyy) 11/30/99 4. Date of this report (m/d/yyyy) 2/16/2000

5. Describe event or problem

o/o weakness + vomiting blood  
x1 + melena x5.  
UGIB

6. Relevant tests/laboratory data, including dates

HGB 9.4 on 12/1/99  
HCT 30.2

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTU WISSD

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeled, if known)

#1 Ibuprofen  
#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 200mg OTC  
#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (month or best estimate)

#1 fx daily  
#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 Shoulder pain  
#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

6. Lot # (if known) 7. Exp. date (if known)

#1 \_\_\_\_\_ #1 \_\_\_\_\_  
#2 \_\_\_\_\_ #2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply  
#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_ #2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

taking another OTC analgesic,  
possibly another NSAID

**D. Suspect medical device**

1. Brand name \_\_\_\_\_

2. Type of device DSS

3. Manufacturer name & address MAY 02 2000

4. Operator of device

health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (m/d/yyyy) \_\_\_\_\_

6. model # RECEIVED

7. If implanted, give date (m/d/yyyy) \_\_\_\_\_

catalog # MAY 02 2000

8. If explanted, give date (m/d/yyyy) \_\_\_\_\_

serial # MEDWATCH CTU

lot # \_\_\_\_\_

other # \_\_\_\_\_

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

VA HOSPITAL (119)  
7400 MERTON MINTER BLVD.  
SAN ANTONIO, TX 78284

2. Health professional?  yes  no

3. Occupation Pharm D

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178



For VOLUNTARY reporting of health professionals of adverse events and product problems

Form Approved 248 No. 11-2-20 Expires 2/21/02 See 248 Statement on reverse

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page      of      CDER

CDER

Trace unit sequence # 121917

### A Patient information

1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: <u>43</u>	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight — lbs or — kgs
-------------------------------------	---	---	--------------------------------

### B Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization (initial or prolonged)	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: <u>Severe.</u>

3. Date of event (mandatory): 1/3/2000

4. Date of this report (mandatory): 03/21/00

5. Describe event or problem

Description of reaction: GI Bleeding

Treatment: Hospitalization.  
Fluid resuscitation.  
Epinephrine, antiemetics,  
IV pepaid/po prevacid.

HCT decreased into 40s during hospitalization & remained stable there.

6. Relevant tests/laboratory data, including dates

HCT : 52 on admittance.

## RECEIVED

MAY 08 2000

### MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Had GI bleeding 5 years ago.  
Actively oozing Mallory-Weiss tear  
Probably alcoholism

NKDA

Mail to: **FDA** MEDWATCH  
5800 Fishers Lane  
Rockville, MD 20852-0787

OR FAX to:  
1-800-FDA-0178

### C Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Ibuprofen

#2

2. Dose, frequency & route used

#1 200 mg - oral

#2 6 tablets.

3. Therapy dates (if unknown, give duration) (month/year)

#1 day of admittance.

#2

4. Diagnosis for use (indication)

#1

#2

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

### D Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (month/year)

6. Model # DSS

7. If implanted, give date (month/year)

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E Reporter

1. Name, address

[redacted], MS, RPh  
Department of Pharmacy  
[redacted] Hospital  
[redacted] Ave  
[redacted]

2. Health professional?  yes  no

3. Occupation RPH

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CTU/121917



# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting  
by health professionals of adverse  
events and product problems  
Internet Submission - Page 1

Form Approved: OMB No. 0910-0281 Expires: 8/31/00  
See OMB statement on reverse

FDA Use Only  
Triage unit sequence # 122210

CDER  
CDER

**A. Patient information**

1. Patient identifier 194052 In confidence	2. Age at time of event: 17 Years or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or 63.6 kgs
--	---	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input checked="" type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 05/05/2000

4. Date of this report (mm/dd/yyyy) 05/11/2000

5. Describe event or problem

Received naproxen for few days s/p dental extraction. Naproxen made him nauseous. Mom instructed patient to take ibuprofen q6h for pain. 8 days post-procedure, patient complained of bloody stools. Later that evening, mom heard a crash and found the patient unresponsive on the floor in a pool of blood -presumably a stool-. The patient was transported to the ER, received fluid bolus for dehydration, and admitted to the ICU. Upper GI showed duodenal ulcer. The patient continued to bleed, despite drug therapy and transfusions, and is scheduled for surgery today.

**DSS**  
MAY 12 2000

6. Relevant tests/laboratory data, including dates

Hemoglobin on admission = 12.3, dropped to 7s-9s over next few days, despite transfusions BMP normal, Coags and factors normal

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

maternal hx of vonWillebrands disease

**C. Suspect medication(s)**

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 Anaprox / /	
#2 Advil / /	
2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 /q12h /Oral	#1 From 05/01/2000 To (or best estimate) 05/05/2000
#2 /q6h /Oral	#2 05/03/2000 - 05/08/2000
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced
#1 post dental extraction pain	#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 post dental extraction pain	#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # (for product problems only)	
-	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (mm/dd/yyyy)

6. model #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)

yes  no  returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name \_\_\_\_\_ phone \_\_\_\_\_

PharmD \_\_\_\_\_  
Hospital \_\_\_\_\_ Street \_\_\_\_\_

United States \_\_\_\_\_

2. Health professional?  
 yes  no

3. Occupation  
Pharmacist

4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20862-0778  
or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 122210



Voluntary reporting  
by health professionals of adverse  
events and product problems

Form Approved: OMB No. 0918-0291 Expires: 8/31/00  
See OMB statement on reverse

FDA Use Only

Triage unit  
sequence # 123457

Internet Submission - Page 1

CDEP

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

**A. Patient information**

1. Patient identifier 373,372 <small>In confidence</small>	2. Age at time of event: 36 Years or Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	--	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 04/25/2000

4. Date of this report (mm/dd/yyyy) 05/31/2000

5. Describe event or problem

Patient admitted for severe iron deficiency anemia and gastric ulcer believed to be caused by NSAID us [ASA-Excedrin ES/Motrin]. NSAIDs d/cd, and ulcer treated with Omeprazole. Caused pt admission to hospital x 2days. Patient transfused with 4 units of PRBCs.

6. Relevant tests/laboratory data, including dates

Endoscopy showed a 1.2cm prepyloric ulcer with clean base and devoid of visible vessel, adherent clot and active bleeding...4/25 Hgb=4.4, HCT=14.3...4/27 on discharge Hgb=9.1 and HCT=27.9

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Migraines for which patient increased her intake of NSAIDs prior to admission....NKA

**C. Suspect medication(s)**

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration) From To (or best estimate)
#1 Excedrin ES / /	#1 9-12t /div abs /daily /Oral	#1 01/01/1995 - 04/25/2000
#2 Motrin /200mg /	#2 3 /div tabs /daily /Oral	#2 01/01/1995 - 04/25/2000
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced	
#1 Migraines [used for years]	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Migraines [used for years]	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		
- - -		
10. Concomitant medical products and therapy dates (exclude treatment of event)		

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (mm/dd/yyyy)

6. model # JUN 01 2000

catalog # MEDWATCH

serial # SSU

lot # JUN - 2 2000

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)

yes  no  returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name \_\_\_\_\_ phone # \_\_\_\_\_

\_\_\_\_\_ Medical Center. \_\_\_\_\_ Drive

\_\_\_\_\_ United States \_\_\_\_\_

2. Health professional?  yes  no

3. Occupation Pharmacist

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20857  
or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

C7U123457



# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting  
by health professionals of adverse  
events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/08  
See OMB statement on www.gsa.gov  
FDA Use Only  
Trace unit sequence # **124732**

CDER

Page \_\_\_ of \_\_\_

**A Patient information**

1. Patient identifier [redacted] In confidence	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or 43 kg
--	---	---	--------------------------------------

**B Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> Other: <u>Severe</u>	

3. Date of event (m/d/yyyy) 6/6/00

4. Date of this report (m/d/yyyy) 6/16/00

5. Describe event or problem

Coffee-ground emesis  
melanotic stools  
dizziness/fatigue  
to

Tx: Pepid  
PRBC  
IV f

6. Relevant tests/laboratory data, including dates

**DSS**

Guac

Coffee ground emesis

EGD / meliory - weiss tear

JUN 28 2000

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA

w/o EtOH Abuse

**C Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 Fbu Profen

#2

2. Dose, frequency & route used

#1 200mg - 10 tabs/day

#2

3. Therapy dates (if unknown give duration) (month or best estimate)

#1 1 week

#2

4. Diagnosis for use (indication)

#1 low back pain

#2

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (m/d/yyyy)

6. If implanted, give date (m/d/yyyy)

7. If implanted, give date (m/d/yyyy)

8. If implanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**F Reporter**

1. Name, address

[redacted] MS, RPh  
Hospital Pharmacy  
[redacted] Ave

2. Health professional?

yes  no

3. Occupation

RPh

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

**FDA** Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

FDA Form 3500 (8/00) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV124732



TM WYETH  
WYET  
BOX 8  
PHILA

INDIVIDUAL Safety Report

MEDWATCH



CTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ7876227JUN2000

UF/Dist report #

FDA Use Only

of 2

x B.6 - Relevant test/laboratory data, including dates (Continuation)

Test Name	Date	Result	Normal Range
Platelet count		Low (date and values unknown)	-
White blood cell count		Low	-

JUL 13 2000



\*3529671-9-00-01\*

EVENTS REPORTING PROGRAM

of 1

Approved by the FDA on 09/24/1999

Mfr report # HQ2132806APR2000

UF/Dist report #

FDA Use Only

**A. Patient information**

1. Patient identifier [redacted]	2. Age at time of event: or 41Yr Date of Birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 160 lbs or kgs
-------------------------------------	---	---	-----------------------------------

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known) # 1 ADVIL # 2	
2. Dose, frequency & route used # 1 2-14 tablets daily, Oral # 2	3. Therapy dates (if unknown, give duration) # 1 1 Mth # 2
4. Diagnosis for use (indication) # 1 Sinus headache # 2	5. Event abated after use stopped or dose reduced # 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply # 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known) # 1 19LG639 # 2	7. Exp date (if known) # 1 # 2
8. Event reappeared after reintroduction # 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply # 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**B. Adverse event or product problem**

1. <input checked="" type="checkbox"/> Adverse event	<input type="checkbox"/> Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization-initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr)	UNK	4. Date of this report (mo/day/yr)	07/11/2000
------------------------------	-----	------------------------------------	------------

5. Describe event or problem  
 A 41-year-old female consumer reported that she experienced stomach pains and blood in her stool while taking the product a year ago. She took 2-14 tablets daily for sinus headaches for 1 month. Her symptoms abated after she stopped taking the product. She was advised to contact her physician concerning her symptoms and proper dosage of the product. No other symptoms were reported. Internal Whitehall-Robins #00-0150-013.

6. Relevant tests/laboratory data, including dates  
 None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
 UNK

**G. All manufacturers**

1. Contact office - name/address WHITEHALL-ROBINS Medical Department 5 Giralda Farms Madison, NJ 07940-0871		2. Phone number 9736605500
4. Date received by manufacturer (mo/day/yr) 02/01/2000		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #	5. (A)NDA 18-989 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes	8. Adverse event term(s) Abdominal pain NOS Gastrointestinal haemorrhage NOS
7. Type of report <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #	9. Mfr. report number HQ2132806APR2000	

**E. Initial reporter**

1. Name & address [redacted] Avenue, Apt. [redacted] US		phone # [redacted]
JUL 13 2000		

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
--	---------------	---



**A. Patient information**

1. Patient identifier [REDACTED]	2. Age at time of event: or 51Yr Date of Birth: [REDACTED]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 260 lbs or kgs
-------------------------------------	--	---	-----------------------------------

**B. Adverse event or product problem**

1.  Adverse event  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization-initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 09/02/1998

4. Date of this report (mo/day/yr) 07/11/2000

5. Describe event or problem

A 51 year old man experienced dizziness and an episode of fainting after years of using the product on an 'as needed' basis. As a result of dizziness, the reporter fell and fractured his right ankle. On 09-02-98, a year and 2 months prior to this report, he was hospitalized and blood tests confirmed anemia and subsequent diagnosis of bleeding ulcer to be caused by product use. Medical records were received on 01-04-00. At the time of report, the consumer reported that he is still experiencing ankle pain and seeing his physician. No further symptoms or sequelae were reported. Lab Values received), Medical Records (received 01-04-00), Admission date (09-02-98), Discharge date (09-05-98), Treatment 09-02: bleeding ulcer cauterized. Previous use was uneventful. Internal WHR # 99-0150-128.

6. Relevant tests/laboratory data, including dates

None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 ADVIL

#2

2. Dose, frequency & route used

#1 2-4 tablets (max 6) day, Oral

#2

3. Therapy dates (if unknown, give duration)

#1 10 years

#2

4. Diagnosis for use (indication)

#1 Headache NOS, Pain NOS

#2

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known) #1

7. Exp date (if known) #1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event) See following page.

**D. All manufacturers**

1. Contact office - name/address

WHITEHALL-ROBINS  
 c/o WYETH LABS (RA)  
 240 N Radnor-Chester  
 St. Davids, PA 19087

2. Phone number 6109024647

3. Report source (check all that apply)

foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer (mo/day/yr) 11/03/1999

5. (A)NDA 18-989  
 IND #  
 PLA #  
 pre-1938  yes  
 OTC product  yes

6. If IND, protocol #

7. Type of report

5-day  15-day  
 10-day  periodic  
 initial  follow-up #

8. Adverse event term(s)  
 Gastric ulcer haemorrhage  
 Dizziness (exc vertigo)  
 Syncope

9. Mfr. report number HQ7861426JUN2000

**E. Initial reporter**

1. Name & address

Mr. [REDACTED] phone # [REDACTED]  
 [REDACTED] Med. Ctr. [REDACTED]  
 [REDACTED] Avenue [REDACTED] US

JUL 13 2000

2. Health professional?  yes  no

3. Occupation

4. Initial reporter also sent report to FDA  yes  no  unk



Health professionals of adverse events and product problems

FDA Use Only  
Triage unit sequence # 125818

Page \_\_\_ of \_\_\_ CDER

**A. Patient information**

1. Patient identifier: 7849  
in confidence

2. Age at time of event: \_\_\_\_\_  
or Date of birth: \_\_\_\_\_

3. Sex:  female  male

4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):

death  life-threatening  hospitalization - initial or prolonged

disability  congenital anomaly  required intervention to prevent permanent impairment/damage  other: \_\_\_\_\_

3. Date of event (mo/day/yr): \_\_\_\_\_

4. Date of this report (mo/day/yr): \_\_\_\_\_

5. Describe event or problem

Self medicated w/ Motrin for pain, Black, continued melana for 1 month.  
Pt received Sandostatin, Vit K, and Start Prevacid

6. Relevant tests/laboratory data, including dates

RECEIVED  
JUL 17 2000  
MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking, drug use, hepatic/renal dysfunction, etc.):

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeier, if known)

#1 Naprosyn  
#2 MOTRIN, ASPIRIN

2. Dose, frequency & route used

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration from to (or best estimate))

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 PAIN  
#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  does apply  
#2  yes  no  does apply

6. Lot # (if known)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  does apply  
#2  yes  no  does apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS

4. Operator of device

health professional  
 lay user/patient  
 other:

5. Expiration date (mo/day/yr)

JUL 18 2000

6. model # \_\_\_\_\_  
catalog # \_\_\_\_\_  
serial # \_\_\_\_\_  
lot # \_\_\_\_\_  
other # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

[Redacted]

2. Health professional?  yes  no

3. Occupation

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

TM WYETH  
WYETH

WYETH  
BOX 82  
PHILAC



\*3529785-3-00-02\*

# MEDWATCH

TS REPORTING PROGRAM

of 2

Approved by the FDA on 09/24/1999

Mfr report # HQ7861426JUN2000

UF/Dist report #

FDA Use Only

x C.10 - Concomitant medical products and therapy dates (exclude treatment of event)

( Continuation )

Therapy Name

Dose, frequency, & route used

Therapy Dates

NONE

UNK

UNK

JUL 13 2000



PRODUCTS REPORTING PROGRAM

Mfr report # HQ9178431JUL2000

UF/Dist report #

FDA Use Only

ge 1 of 2

**A. Patient information**

1. Patient identifier [redacted]	2. Age at time of event: or UNK Date of Birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or kgs
-------------------------------------	--	---	-----------------------------------

**B. Adverse event or product problem**

1.  Adverse event  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization-initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> recovered	<input checked="" type="checkbox"/> other: medically important

3. Date of event (mo/day/yr) 07/03/2000

4. Date of this report (mo/day/yr) 08/01/2000

5. Describe event or problem

Information has been received on 28-JUL-2000 concerning a male patient who had taken Advil tablets (400mg, 3 times everyday) beginning on 28-JUN-2000 to 03-JUL-2000 for Pyrexia. The patient had recent heart bypass surgery and was discharged to home on 26-JUN-2000. He began experiencing a fever on 28-JUN-2000 and Advil therapy was initiated. Concomitant therapy was not reported. On 03-JUL-2000, the patient was taken to the emergency room after fainting (Blood pressure reading was 90/30 mmHG). He was diagnosed with acute renal failure (Renal failure acute) and was started on dialysis 3 times per week. The patient was also diagnosed, via an endoscopy, with a bleeding duodenum ulcer (Ulcer NOS) causing a GI Bleed (Gastrointestinal haemorrhage NOS) which required 4 units of blood to be transfused. The patient reported that his physician related his renal failure and bleeding ulcer to the use of Advil. These events found to be Medically important.

6. Relevant tests/ laboratory data, including dates  
See following page.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PAST CONDITIONS:  
Coronary artery surgery



**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

# 1 ADVIL

# 2

2. Dose, frequency & route used

# 1 400 mg 3x per 1 Day, Oral

# 2

3. Therapy dates (if unknown, give duration)

# 1 06/28/2000 to 07/03/2000

# 2

4. Diagnosis for use (indication)

# 1 Pyrexia

# 2

5. Event abated after use stopped or dose reduced

# 1  yes  no  doesn't apply

# 2  yes  no  doesn't apply

6. Lot # (if known)

# 1

# 2

7. Exp date (if known)

# 1

# 2

8. Event reappeared after reintroduction

# 1  yes  no  doesn't apply

# 2  yes  no  doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**G. All manufacturers**

1. Contact office - name/address

WHITEHALL-ROBINS  
c/o WYETH LABS (RA)  
240 N Radnor-Chester  
St. Davids, PA 19087

Jill Robinson

2. Phone number  
6109024647

3. Report source (check all that apply)

foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer (mo/day/yr)  
07/28/2000

5. (A)NDA 18-989  
IND #  
PLA #  
pre-1938  yes  
OTC product  yes

6. If IND, protocol #

7. Type of report

5-day  15-day  
 10-day  periodic  
 initial  follow-up #

8. Adverse event term(s)  
Renal failure acute  
Ulcer NOS  
Gastrointestinal haemorrhage NOS

9. Mfr. report number  
HQ9178431JUL2000

**E. Initial reporter**

1. Name & address  
[redacted], Mr. [redacted] phone # [redacted]  
[redacted] D-1116 US

2. Health professional?  
 yes  no

3. Occupation

4. Initial reporter also sent report to FDA  
 yes  no  unk

DSS  
AUG 04 2000

AUG - 3 2000

WYETH

INDIVIDUAL SAFETY REPORT

# MEDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ9178431JUL2000

UF/Dist report #

FDA Use Only



\*3541202-6-00-02\*

2 of 2

Box B.6 - Relevant test/laboratory data, including dates (Continuation)

<u>Test Name</u>	<u>Date</u>	<u>Result</u>	<u>Normal Range</u>
Blood pressure	07/02/2000	90/30mmHG	-
Endoscopy NOS	00/00/2000	duodenum ulcer	-

AUG - 3 2000

DSS

AUG 04 2000



**A. Patient information**

1. Patient identifier # 6075	2. Age at time of event: 66	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 105 lbs or 45 kg
---------------------------------	--------------------------------	---	-------------------------------------

**B. Adverse event or product problem**

Adverse event and/or  Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply):

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

Date of event: 1/26/00      4. Date of this report: 1/27/00

Describe event or problem

pt admitted with dyspnea, ↓ appetite.  
 He approx two weeks prior for bilateral pneumonia. Taking ibuprofen for flu symptoms. NG lavage ⊖, ⊕ orthostasis, home ⊕ stool, EGD: 2 antral ulcers, clo test positive. Admitted to ICU, lansoprazole, clarithromycin, amoxicillin, two units PRECS

Relevant tests/laboratory data, including dates

Hct 36 → 24

Other relevant history, including preexisting medical conditions (e.g., allergies, etc., pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

pneumonia, HTN, drug abuse, CAD.

CTU 127441  
Severity: Severe      Probability:

**C. Suspect medication(s)**

1. Name (give labeled strength & millage if applicable) #1: ibuprofen	2. Dose, frequency & route used #1: 200mg QID x #2: 1 week	3. Therapy dates (include start/stop dates) #1: _____ #2: _____
4. Diagnosis for use (indication) #1: _____ #2: _____	5. Event abated after use stopped or dose reduced #1: <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> see	6. Event reappeared after reintroduction #1: <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> see
6. Lot # (if known) #1: _____ #2: _____	7. Exp. date (if known) #1: _____ #2: _____	8. NDC # (for product problems only) #1: _____ #2: _____
10. Concomitant medical products and therapy dates (exclude treatment of event)		

**D. Suspect medical device**

1. Brand name	2. Type of device
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
<b>RECEIVED</b>	
5. Expiration date (if any)	6. If implanted, give (implant) site
7. If implanted, give (implant) site	8. If implanted, give (implant) site
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone # Pharm D Baltimore VAMC 10 North Greene Street Baltimore, Maryland 21201		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Clinical Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user/patient <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		

**FDA** Mail to: MEDWATCH      or FAX to:  
5600 Fishers Lane      1-600-FDA-0178  
Rockville, MD 20852-9787

# ADR Probability Scale

(Naranjo, CA et al. CPT 1981;30:239-45)

To assess the adverse drug reaction, please answer the following questionnaire  
circle the pertinent score



	YES	NO	DO NOT KNOW	SCORE
1. Are there previous <u>conclusive</u> reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a <u>specific</u> antagonist was administered?	+1	-1	0	
4. Did the adverse reaction appear when the drug was readministered?	+2	-1	0	
5. Are there any alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in <u>any</u> previous exposure?	+1	0	0	
10. Was the adverse reaction confirmed by objective evidence?	+1	0	0	

TOTAL SCORE

## CLASSIFICATION OF ADVERSE DRUG REACTION

Please circle appropriate probability category

- 1. Definite ≥ 9
- 2. Probable 5-8
- 3. Possible 1-4
- 4. Doubtful ≤ 0

ADR ID CODE:



**Voluntary** reporting  
by health professionals of adverse  
events and product problems

CDER

Form Approved: OMB No. 0910-0201 Expires 12/31/00  
See OMB statement on reverse

FDA Use Only H Pad

Tracing and  
compliance # **127924**

**THE FDA MEDICAL PRODUCTS REPORTING PROGRAM**

Page **L** of **L**

CDER

**A. Patient information**

1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: <b>99</b>	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------------	--	--	--------------------------------------

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyyy) **7-16-00**

4. Date of this report (m/d/yyyy) **8-11-00**

5. Describe event or problem

*pt. admitted thru ER  
2° epigastric distress  
& hematemesis; upper  
GI bleed.*

6. Relevant tests/laboratory data, including dates

**RECEIVED**  
AUG 24 2000  
**MEDWATCH CTU**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

*DJD*

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 **Advil** **ADVIL**

#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 *prn*

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 **DJD**

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (m/d/yyyy)

6. Model # **DSS**

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

**Health System**

2. Health professional?  yes  no

3. Occupation **Pharmacist**

4. Also reported to

manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CTU 127924

**FDA** Mail to: **MEDWATCH** or FAX to: **MEDWATCH**

5600 Fishers Lane, Rockville, MD 20852-1418 1-800-FDA-0178

**MEDWATCH**  
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report



\*3560401-0-00-01\*



McNeil Consumer Healthcare  
Fort Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_ of \_\_\_

**A. Patient information**

1. Patient identifier In confidence	2. Age at time of event: 30 mo Date of birth:	3. Sex ( ) female (X) male	4. Weight lbs or 13 kgs
--	---	----------------------------------	----------------------------------

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known) #1 Children's Motrin Ibuprofen Oral Suspen #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 2/2/99-2/3/99; approx 7 doses #2	
2. Dose, frequency & route used #1 150 mg, po #2		4. Diagnosis for use (indication) #1 fever #2	
6. Lot # (if known) #1 unknown #2		7. Exp. date (if known) #1 unknown #2	
9. NDC # - for product problems only (if known)		5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
10. Concomitant medical products and therapy dates (exclude treatment of event) unspecified TYLENOL product, AMOXIL (Sect B7 cont): rec'd transfusion of PRBC. On 2/5/99, post transfusion, H&H increased to 9 & 26. Pt DC'd 2/8/99. Principal dx: (1) upper GI bleed, (2) ANEMIA, (3) gastritis w/ hemorrhage secondary to Motrin.		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	

**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
( ) death (mo/day/yr)	( ) congenital anomaly
( ) life-threatening	( ) required intervention to prevent permanent impairment/damage
(X) hospitalization - initial or prolonged	( ) other:
3. Date of event (mo/day/yr) 2/3/99	4. Date of this report (mo/day/yr) 08/17/00

5. Describe event or problem

Consumer alleges that the use of Children's Motrin® Ibuprofen Oral Suspension was associated w/ GASTROINTESTINAL HEMORRHAGE (GI bleeding) in her son 16 months ago. Consumer reports giving son Children's Motrin® Oral Suspension for 2.5 days. Child reportedly vomitted black, coffee-like grains with clots (HEMATEMESIS). On way to ER, consumer reports child's eyes rolled back in head, legs & arms went limp, & head hanging (HYPOTONIA). Pt rec'd blood transfusion & was hospitalized. Pt was DC'd. An unknown time after, consumer reports child had endoscopy performed by specialist. Results unknown. Subsequent to event, consumer reports child had a HERNIA, has developed poor eating habits, is thin, & must drink LACTAID® because he can no longer digest regular milk. Consumer reports child experiences stomach pain (ABDOMINAL PAIN) now. Addl info rec'd 7/17/00: Med Rec authorization form completed by consumer indicates child experienced GI bleeding GASTRITIS w/ hemorrhage. Addl info rec'd 8/15/00: Med records indicate pt (See Sect B6)

6. Relevant tests/laboratory data, including dates

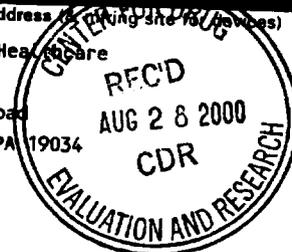
2/3/99 (23:30): PLT=210, Hgb=6.4, HCT=18.4; 2/5/99 Upper GI series nl; 2/7/99 Hgb=9.5, HCT=27.2, PLT=189 (Sect B5 cont); presented to the ER w/ hx of vomiting times six, bloody, also passing dark stools. Pt had been (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hx of febrile seizure at age 1 and 1/2; NKDA (Sect B6 cont) taking Motrin since 2/2/99 for fever (total approx 7 doses of 1 and 1/2 teaspoonsful). In the ER, NG tube was inserted & saline lavage was given & tested for presence of blood, which was (+). Stool was heme-occult (+). Pt was started on CARAFATE®, PEPCID®, & Lactated Ringer's. Pt (See Sect C10)

**G. All manufacturers**

1. Contact office - name/address (including site no. if known) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303
4. Date received by manufacturer (mo/day/yr) 08/15/00		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature (X) consumer  ( ) health professional ( ) user facility  ( ) company representative ( ) distributor  DSS
6. If IND, protocol #	5. (A) NDA # 20-516 IND # PLA # pre-1938 ( ) Yes  OTC product (X) Yes	8. Adverse event term(s) AUG 29 2000 HEMORRHAGE GI HYPOTONIA PAIN ABDOMINAL ANEMIA HEMATEMESIS HERNIA GASTRITIS
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic ( ) Initial (X) follow-up # 2	9. Mfr. report number 1375221A	



**E. Initial reporter**

1. Name, address & phone # [redacted] MD [redacted] Hospital [redacted] Street [redacted]		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk	
2. Health professional? (X) Yes ( ) No	3. Occupation physician	AUG 28 2000	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report



\*3561793-9-00-01\*

DWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report #	HQ7339414JUN2000
UF/Dist report #	
FDA Use Only	

PHILADELPHIA, PA 19101

Page 1 of 2

**A. Patient information**

1. Patient identifier	2. Age at time of event: or 3Yr	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 35 lbs or kgs
Date of Birth:			

**B. Adverse event or product problem**

1.  Adverse event       Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization—initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 03/03/2000      4. Date of this report (mo/day/yr) 08/23/2000

5. Describe event or problem

A female reporter stated that her 3-year-old girl had "GI bleeding" while taking the product. She was given 1 teaspoonful of the product for a high fever. Concomitant meds included Zantac (ranitidine) and Propulsid (cisapride) for gastroesophageal reflux. At the time of the call, 3 days later, the girl had no symptoms of GI bleeding. No further symptoms were reported. Has used the product in the past without incident. Internal Whitehall-Robins # 00-0171-011.

6. Relevant tests/laboratory data, including dates

None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS:  
Oesophageal reflux

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

# 1 CHILDREN'S ADVIL SUSPENSION

# 2

2. Dose, frequency & route used

# 1 1 tsp, Oral

# 2

3. Therapy dates (if unknown, give duration)

# 1 1 dose

# 2

4. Diagnosis for use (indication)

# 1 Pyrexia

# 2

5. Event abated after use stopped or dose reduced

# 1  yes  no  doesn't apply

# 2  yes  no  doesn't apply

6. Lot # (if known) # 199262      7. Exp date (if known) # 1

# 2      # 2

8. Event reappeared after reintroduction

# 1  yes  no  doesn't apply

# 2  yes  no  doesn't apply

9. NDC # — for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

See following page.

**G. All manufacturers**

1. Contact office — name/address

WHITEHALL-ROBINS  
c/o WYETH LABS (RA)  
240 N Radnor-Chester  
St. Davids, PA 19087

Jill Robinson

2. Phone number

6109024647

3. Report source (check all that apply)

foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer (mo/day/yr) 03/07/2000

5. (A)NDA 20-589  
IND #  
PLA #  
pre-1938  yes  
OTC product  yes

6. If IND, protocol #

7. Type of report

5-day     15-day  
 10-day     periodic  
 initial     follow-up #

8. Adverse event term(s)

Gastrointestinal haemorrhage  
NOS

9. Mfr. report number

HQ7339414JUN2000

**E. Initial reporter**

1. Name & address      phone #

Ms.  
Pediatrics  
Road  
US

AUG 28 2000

2. Health professional?  yes  no

3. Occupation

4. Initial reporter also sent report to FDA  yes  no  unk

Individual Safety Report



\*3561793-9-00-02\*

EDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ7339414JUN2000

UF/Dist report #

FDA Use Only

PHILADELPHIA, PA 19101

Page 2 of 2

C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

<u>Therapy Name</u>	<u>Dose, frequency, &amp; route used</u>	<u>Therapy Dates</u>
PROPULSID	2.8 mls tid, Oral	UNK
ZANTAC	2 mls bid, Oral	UNK

AUG 28 2000

Individual Safety Report



\*3561836-2-00-01\*

BOX 8299  
PHILADELPHIA, PA 19101

**ADWATCH**

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report #	HQ8966225JUL2000
UF/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient identifier [redacted]	2. Age at time of event: or 5Yr Date of Birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 42 lbs or kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> life-threatening	<input type="checkbox"/> hospitalization—initial or prolonged	<input type="checkbox"/> recovered
<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	<input type="checkbox"/> required intervention to prevent permanent impairment/damage	<input type="checkbox"/> other:
3. Date of event (mo/day/yr)	12/04/1999	4. Date of this report (mo/day/yr)	08/23/2000
5. Describe event or problem			
<p>The reporter stated that her daughter experienced vomiting blood and abdominal pain about 10 hours following the last dose of the product which was used concomitantly with a single dose of hydrocodone syrup. Within 10 minutes after the event, she was brought to a local ER, where when experienced 2 additional episodes of vomiting blood. In the ER a blood test revealed low r.b.c. count. She was monitored closely in the ER for about 1 hour and then admitted. She was given Zantac 3 ml bid and spent about 12 hours in the hospital prior to discharge. A discharge blood test confirmed low r.b.c. count (specific data unknown for either of the blood tests). On the discharge, the child was prescribed Zantac for the next 2 weeks and bland diet. The treating physician believed that the event was related to Advil use and advised no further use. At the time of report, 27 days after the event, the child still occasionally complains of stomach pain. On those occasions she is administered Zantac, which relieves the</p> <p style="text-align: center;">(cont'd)</p>			
6. Relevant tests/laboratory data, including dates			
See following page.			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
UNK			

C. Suspect medication(s)	
1. Name (give labeled strength & mfr/labeler, if known)	
# 1 CHILDREN'S ADVIL SUSPENSION	
# 2 HYDROCODONE	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
# 1 1.5 tsp q8h-12h, Oral	# 1 4 days
# 2 0.5 tsp prn, Oral	# 2 1 dose
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
# 1 Pyrexia, Rigors, Pain NOS	# 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
# 2 Cough	# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp date (if known)
# 1	# 1
# 2	# 2
8. Event reappeared after reintroduction	
# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. All manufacturers	
1. Contact office - name/address	2. Phone number
WHITEHALL-ROBINS c/o WYETH LABS (RA) 240 N Radnor-Chester St. Davids, PA 19087	6109024647
Jill Robinson	3. Report source (check all that apply)
	<input type="checkbox"/> foreign
	<input type="checkbox"/> study
	<input type="checkbox"/> literature
	<input checked="" type="checkbox"/> consumer
	<input type="checkbox"/> health professional
	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other:
4. Date received by manufacturer (mo/day/yr)	5. (A)NDA 20-589
12/31/1999	IND #
6. If IND, protocol #	PLA #
	pre-1938 <input type="checkbox"/> yes
	OTC product <input checked="" type="checkbox"/> yes
7. Type of report	8. Adverse event term(s)
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	Gastric haemorrhage
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic	Haematemesis
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #	Abdominal pain NOS
9. Mfr. report number	
HQ8966225JUL2000	

E. Initial reporter			
1. Name & address		phone #	
[redacted] Ms. [redacted] Rd.		[redacted]	
		US <b>AUG 28 2000</b>	
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

Individual Safety Report



\*3561836-2-00-02\*

**EDWATCH**

RODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ8966225JUL2000

UF/Dist report #

FDA Use Only

PHILADELPHIA, PA 19101

Page 2 of 2

: B.5 - Describe event or problem ( Continuation )

pain. Medical records have been requested. No further symptoms or sequelae were reported. Internal Whitehall-Robins #99-0171-064.

Box B.6 - Relevant test/laboratory data, including dates ( Continuation )

Test Name

Date

Result

Normal Range

Full blood count

BLOOD TEST REVEALED LOW R.B.C. COUNT.

-

**AUG 28 2000**



# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting  
by health professionals of adverse  
events and product problems  
Internet Submission - Page 1

CDER

Form Approved: OMB No. 0910-0291 Expires: 11/30/00  
See OMB statement on reverse

FDA Use Only  
Triage unit  
sequence # **128960**

### A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 71 Years or Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or 113 kgs
-------------------------------------	---	---	--

### B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 08/22/2000

4. Date of this report (mm/dd/yyyy) 09/12/2000

5. Describe event or problem

Patient presented to PharmD at hotel of VFW convention c/o dizziness and PRBR. Had been taking 10-12 OTC strength ibuprofen per day for 2 days. Forgot Vioxx at home. Taken to VA ER. Hct dec to 26.4. Orthostatic hypotension. GI bleed suspected. Scope done. Inconclusive. Has had h/o GI bleed on NSAIDs in past. Two units of PRBC given. Patient kept in hospital for 3 days. Discharged to home in [redacted]

6. Relevant tests/laboratory data, including dates

Hct 8/22/00 = 26.4

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

h/o gi bleeds OA

### C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Ibuprofen / 200 mg / Unknown #2 / /	2. Dose/Frequency/Route used #1 1000- / 24 hours / Oral #2 / /	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 08/20/2000 - 08/22/2000 #2 -
4. Diagnosis for use (separate indications with commas) #1 OA #2	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	6. Lot # (if known) 7. Exp. date (if known) #1 #1 #2 #2
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	9. NDC # (for product problems only) - -	10. Concomitant medical products and therapy dates (exclude treatment of event) None

### D. Suspect medical device

1. Brand name <b>DSS</b>	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
2. Type of device	5. Expiration date (mm/dd/yyyy)
3. Manufacturer name & address SEP 16 2000 <b>RECEIVED</b> SEP 15 2000 <b>MEDWATCH CTU</b>	7. If implanted, give date (mm/dd/yyyy)
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	8. If explanted, give date (mm/dd/yyyy)
9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

### E. Reporter (see confidentiality section on back)

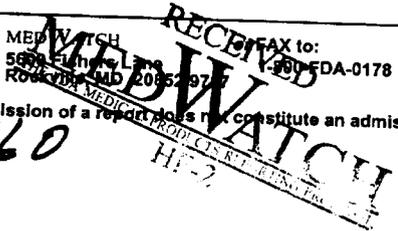
1. Name [redacted] Pharm.D VAMC CS-119 ; 5000 W. National Avenue Milwaukee Wisconsin 53295 United States [redacted] ed. va.gov	2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer <input checked="" type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9777  
FAX to: 1-800-FDA-0178

CTU128960

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



TM  
WYETH  
BOX E  
PHILA



# MEDWATCH

CTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report #	HQ0826811SEP2000
UF/Dist report #	
FDA Use Only	

of 2

## A. Patient information

1. Patient identifier [REDACTED] in confidence	2. Age at time of event: or 54Yr Date of Birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or kgs
--	--	---	-----------------------------------

## B. Adverse event or product problem

1.  Adverse event     Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization—initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 04/17/1998    4. Date of this report (mo/day/yr) 09/20/2000

5. Describe event or problem

Information was received on 03-DEC-1999 from an attorney regarding a 54 Yr old female consumer. Additional information received on 14-SEP-2000, indicated that initial information regarding the adverse event was originally reported on 03-DEC-1999. The patient's concurrent illnesses include a CEPHALEXIN allergy and tobacco use with a past history of umbilical hernia repair, a back operation and measles. The patient received therapy with ADVIL (dose form unspecified) (indication, start date, and stop date were also unspecified). The dose regimen included 6-9 tablets by mouth daily. Concomitant therapy included MELATONIN. On 17-APR-1998 the patient was hospitalized with a perforated abdominal ulcer (Duodenal ulcer perforation) and peritonitis (Peritonitis). Upon admission to the emergency room on 17-APR-1998 the patient had a heart rate of 80 beats per minute and a blood pressure of 120/90 mmHg. A sonogram of the patient's gallbladder was determined to be negative. CT scan of the abdomen (cont'd)

6. Relevant tests/laboratory data, including dates

See following page.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS:  
Drug hypersensitivity; Tobacco abuse

PAST CONDITIONS:  
Umbilical hernia NOS; Operation NOS; Measles



## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 ADVIL #2		3. Therapy dates (if unknown, give duration) #1 UNK #2	
2. Dose, frequency & route used #1 6-9 tablets daily, Oral #2		4. Diagnosis for use (indication) #1 UNK #2	
6. Lot # (if known) #1 #2		7. Exp date (if known) #1 #2	
9. NDC # - for product problems only (if known)		8. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply		10. Concomitant medical products and therapy dates (exclude treatment of event) See following page.	

## G. All manufacturers

1. Contact office - name/address WHITEHALL-ROBINS c/o WYETH LABS (RA) 240 N Radnor-Chester St. Davids, PA 19087 Jill Robinson		2. Phone number 6109024647
4. Date received by manufacturer (mo/day/yr) 09/18/2000		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #		5. (ANDA 18-989) IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input checked="" type="checkbox"/> yes
7. Type of report <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 2		8. Adverse event term(s) Duodenal ulcer perforation Peritonitis
9. Mfr. report number HQ0826811SEP2000		

SEP 21 2000

## E. Initial reporter

1. Name & address [REDACTED] Road, MS. [REDACTED] US		phone # [REDACTED]
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		3. Occupation
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk		

DSS  
SEP 22 2000

SEP 20 2000  
DATE SENT TO FDA



PHILADELPHIA, PA 19101

Box B.5 - Describe event or problem (Continuation)

revealed perforated ulcer. The patient had symptoms of right upper quadrant pain, nausea, and vomiting. The patient was treated by having a partial gastrectomy, Billroth-II, gastrojejunostomy, gastrostomy, and vagotomy to help stop the bleeding due to the perforation. The patient was discharged from the hospital on 25-APR-1998. The patient also continues to experience nausea, "ingestion", bloating and abdominal pain.

Box B.6 - Relevant test/laboratory data, including dates (Continuation)

Test Name	Date	Result	Normal Range
Blood pressure	04/17/1998	120/90 mmHg	-
Computerised tomogram	04/17/1998	scan of the abdomen revealed perforated ulcer	-
Heart rate	04/17/1998	80 beats per minute	-
Ultrasound scan NOS normal	04/17/1998	sonogram of gallbladder was negative	-

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

Therapy Name	Dose, frequency, & route used	Therapy Dates
MELATONIN	3 Tablet 1x per 1 Day, Oral	Continues

SEP 21 2000

DSS

SEP 22 2000



Voluntary reporting of adverse and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/04 See OMB statement on reverse

FDA Use Only

Triage unit sequence # 129558

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

CDER

**A. Patient information**

1. Patient identifier [REDACTED]	2. Age at time of event: 40 or Date of birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 118 lbs or [REDACTED] kgs
-------------------------------------	---	---	--

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death 4/30/00 (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 4/30/00

4. Date of this report (mo/day/yr) 9/20/00

5. Describe event or problem

CONSUMER 40 YR W/F LEFT WORK THUR 4/27/00 IN THE AM COMPLAINING SHE WAS SICK TO STOMACH. CONTINUED SICK LEAVE FRIDAY 4/28/00 CLAIMING SHE HAD STOMACH FLU OR FOOD POISONING. SATURDAY NIGHT SHE CALLED AND LEFT MESSAGE ON SISTERS ANSWERING MACHINE TO CALL WHEN SHE HAD CHANCE SHE WAS SICK. ON 4/30/00 SUNDAY BY THE TIME OF SISTERS ARRIVAL THE CONSUMER WAS DEAD IN BED WITH COFFEE GROUND EMESIS NEAR HER.

THE MEDICAL EXAMINERS OPINION BASED UPON THE AUTOPSY FINDING (SEE ATTACHED) THAT THE DECEDENT CAME TO HER DEATH AS A RESULT OF ACUTE PERITONITIS DUE TO PERFORATED CHRONIC DUODENAL PEPTIC ULCER.

6. Relevant tests/laboratory data, including dates
- Autopsy Diagnosis 5/1/00
- 1 ACUTE PERITONITIS
  - 2 PERFORATED CHRONIC DUODENAL PEPTIC ULCER
  - 3 SECOND CHRONIC DUODENAL PEPTIC ULCER
  - 4 ASPIRATION OF VOMITUS
  - 5 ACUTE BRONCHOPNEUMONIA
  - 6 PULMONARY EDEMA AND CONGESTION
  - 7 CONGESTION OF VISCERA

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

DECEDENT SMOKED AND HAD DENTAL WORK DONE RECENTLY

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 ADUIL 200 MG TABS. NUMEROUS EMPTY CARTONS

#2 FOUND IN APT & CAR. ADUIL USED AT LEAST SINCE 1997 ACCORDING TO BROTHER

2. Dose, frequency & route used

#1 DOSE-UNK, FREQ-UNK

3. Therapy dates (if unknown, give duration) (mo/day/yr)

#1 1997 ACCORDING TO BROTHER

4. Diagnosis for use (indication)

#1 UNKNOWN

5. Event abated after use stopped or does reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

-

10. Concomitant medical products and therapy dates (exclude treatment of event)

PEPCID AC - THERAPY DATES UNKNOWN

NUMEROUS EMPTY CARTONS FOUND IN APT & CAR

**D. Suspect medical device**

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (mo/day/yr)

6. model #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

[REDACTED] APT [REDACTED]  
[REDACTED] ROAD  
[REDACTED] MD  
TELEPHONE [REDACTED]

2. Health professional?  yes  no

3. Occupation  
PHARMACIST  
RETIRED FROM FDA

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CTU129558

SEP 28 2000

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

RECEIVED

SEP 27 2000

MEDWATCH CTU



JUSTICE AND PUBLIC SAFETY DIVISION  
OFFICE OF THE MEDICAL EXAMINER OF [REDACTED] COUNTY  
FORENSIC CENTER

[REDACTED] Street P.O. Box [REDACTED] Tel: [REDACTED] Fax: [REDACTED]

MEDICAL EXAMINER'S REPORT

[REDACTED]  
[REDACTED] COUNTY, [REDACTED]

DSS

SEP 28 2000

The post-mortem examination was performed by [REDACTED] M.D., Chief Medical Examiner, beginning at 10:25 a.m., on 5-1-00; at the [REDACTED] County Forensic Center, [REDACTED] under the written authorization of [REDACTED], Justice of the Peace, Precinct [REDACTED] County, [REDACTED]

**EXTERNAL EXAMINATION:**

The body was that of a well developed, fairly well nourished 40 year-old white woman measuring 69 inches in length and weighing 118 pounds. There was fixed rigor mortis and posterior dependent lividity. The head was symmetrical and covered with dark brown hair measuring up to 10 inches in length. The eyes were gray; the pupils round and equal and the sclerae were pale. The nose, lips and ears were intact. The mouth contained natural teeth in good condition and a moderate amount of green-brown vomitus material. The neck was short and thin. The chest was proportionate and symmetrical. The breasts were small. The abdomen was moderately distended. The external genitalia were those of an adult woman. The pubic hair was female in distribution. The lower and upper extremities were symmetrically developed and intact. The back was unremarkable. There was no external evidence of traumatic injury.

**INTERNAL EXAMINATION:**

The usual Y-shaped incision was made. The skin and subcutaneous tissue at the level of the umbilicus measured 1/4 inch in thickness. The breast tissue was mainly adipose tissue. The rib cage was intact. The pleural cavities were free of fluid and adhesions. The pericardial sac was intact and contained a scanty amount of serous fluid. The diaphragm was intact. The abdominal cavity contained approximately 2 quarts of brown-green purulent fluid. The serosal peritoneal surfaces were covered with a thin layer of purulent exudate. There was a perforated duodenal ulcer





[REDACTED]

DSS

[REDACTED]

PAGE 2

as described below. Otherwise, <sup>SEP 28 2000</sup> the thoracic and abdominal viscera were intact and in their usual anatomic relationships. The appendix was present.

HEART:

The heart weighed 350 grams. The epicardium was smooth and glistening. The coronary arteries were normal in distribution and free of atherosclerosis. The myocardium was red-brown. The endocardium was thin and transparent. The heart valves were normal in size and in shape. The foramen ovale was closed. The coronary ostia were patent. The ascending aorta was elastic and pliable. The greater veins were thin-walled and patent.

LUNGS:

The lungs weighed together 1410 grams. They were markedly heavy and bulky, but normal in shape and configuration. The pleural surfaces were smooth and glistening. The tracheobronchial tree contained an abundant amount of frothy pink fluid intermixed with a moderate amount of aspirated vomitus material. On sectioning of the lungs the cut surfaces were dark red-brown and markedly congested. There was early bronchopneumonic consolidation of the posterior portions of both lower lobes. The pulmonary arterial tree was free of thromboemboli.

LIVER:

The liver weighed 1620 grams. The capsular surface was covered with a thin layer of purulent exudate. On sectioning of the liver the cut surfaces were tan-brown and of normal consistency. The gallbladder was filled with black-green bile.

SPLEEN:

The spleen weighed 150 grams. The capsular surface was covered with a thin layer of purulent exudate. On sectioning, the parenchyma was red-purple and with indistinct malpighian bodies.

KIDNEYS:

The kidneys together weighed 350 grams. They were symmetrical, normal in size and in shape. The capsules stripped easily disclosing a smooth cortical surface. On sectioning, the parenchyma was unremarkable. The ureters were intact. The urinary bladder was empty. The internal genitalia were those of a parous woman. There was no pregnancy. The serosal surfaces were covered with a thin layer of purulent exudate.

PANCREAS AND ADRENAL GLANDS

The pancreas was of normal size and shape. The cut surfaces were lobular, tan and firm. The adrenal glands showed a normal cortical-medullary distribution without focal lesions.

GASTROINTESTINAL TRACT:

The esophagus was lined by extensively autolyzed and partially eroded, bile-stained mucosa. The stomach contained a couple of ounces of a fecaloid brown-greenish fluid. In the anterior wall of the duodenal bulb there was a 1 1/4 inch chronic peptic ulcer which had perforated at its center. This perforation measured 1/2

[REDACTED]

}  
}



[REDACTED]  
[REDACTED]  
PAGE 3

inch in diameter. In addition, in the posterior wall of the duodenal wall there was another chronic peptic ulcer, 5/8 inch in diameter. It had superficially penetrated into the pancreas. The serosal surfaces of the intestinal tract were covered with a thin layer of green-brown purulent exudate. The intestines themselves were unremarkable. The appendix was present. }

HEAD:

In view of the gross findings, and of the clinical history, the brain was not examined.

DIAGNOSES:

1. Acute peritonitis.
2. Perforated chronic duodenal peptic ulcer.
3. Second chronic duodenal peptic ulcer.
4. Aspiration of vomitus.
5. Acute bronchopneumonia.
6. Pulmonary edema and congestion.
7. Congestion of viscera.

OPINION:

It is my opinion, based upon the autopsy findings, that the decedent, [REDACTED] came to her death as a result of Acute peritonitis, due to perforated chronic duodenal peptic ulcer.

151

[REDACTED] M.D.  
Chief Medical Examiner  
[REDACTED]

DSS

SEP 28 2000

129558



1199-21

CDER CDer

Approved by FDA on 10/20/93

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 129667

Page 1 of 1

<b>A. Patient Information</b>		<b>C. Suspect Medication(s)</b>	
1. Patient Identifier	2. DOB: [REDACTED]	3. Sex	4. Weight
[REDACTED]	AGE: 70 yrs	MALE	88.3 kg
<b>B. Adverse Event or Product Problem</b>		1. Name	
1. <input checked="" type="checkbox"/> Adverse Event	<input type="checkbox"/> Product problem	#1: IBUPROFEN	
2. Outcomes attributed to adverse event		2. Dose, frequency & route used	
<input type="checkbox"/> death	<input type="checkbox"/> disability	#1:	
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly	3. Therapy dates	
<input checked="" type="checkbox"/> Hospitalization	<input checked="" type="checkbox"/> required intervention to prevent impairment/damage	#1:	
initial or prolonged	<input type="checkbox"/> other	4. Diagnosis for use (indication)	
3. Date of event	4. Date of this report	5. Event abated after use	
11/18/99	09/18/00	stopped or dose reduced?	
5. Describe event or problem	6. Lot # (if known)	7. Exp. date	8. Event reappeared after reintroduction
GI BLEED SEC IBUPROF GASTRITIS	#1:	#1:	#1: [ ]
6. Relevant test/laboratory data, including dates		9. (Not applicable to adverse drug event reports)	
SEP 28 2000		DSS	
MEDWATCH CTU		SEP 29 2000	
7. Other relevant History, including preexisting medical conditions		10. Concomitant medical products/therapies (exclude treatment)	
Chief Complaint: loose, dark stool		URSODIOL 300MG CAP	
ATTENDING PHYSICIAN: [REDACTED] M.D.		POLIC ACID 1MG TAB	
PLEASE SEE ATTACHED		SULFASALAZINE 500MG TAB	
Mail to: MedWatch		PLEASE SEE ATTACHED	
5600 Fishers Lane		D. Suspect Medical Devices	
Rockville, MD 20852-9787		Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug	
or FAX to: 1-800-FDA-0178		E. Reporter	
FDA Form 3500		1. Name, address & phone #:	
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.		[REDACTED]	
		2. Health professional? <input type="checkbox"/>	
		3. Occupation	
		4. Reported to Mfr. <input type="checkbox"/>	
		PROGRAM ANALYS	
		[NO]	
		5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. <input type="checkbox"/>	

CTU 129667



11/99-21  
129667

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: IBUPROFEN

DATE OF EVENT: 11/18/99

Section B. Part 7. Other Relevant History Continued

History of Present Illness: 70 yo WM describes 36 hours of loose, dark stools without n/v or abdominal pain. Also denies light-headedness, palpitations, and syncope. No chest pain. No SOB. No fever or chills.

He was seen in Hematology/Oncology clinic yesterday where he is followed by Dr. [REDACTED] for CML, and had a CBC drawn, HCT then 38. Today in the ED he was orthostatic c HCT 31. NG lavage had a small amount of coffee-grounds that cleared after ~400cc. Orthostasis resolved following several liters.

Past Medical History: 1)Hypertension. 2)Ulcerative colitis. Followed in GI clinic. Last colonoscopy: advanced to cecum, very tortuous in sigmoid/desc colon; mucosa "atrophic," thick, and friable, with neo-vascularization throughout; no evidence of polyp/mass; biopsies showing chronic inflammatory changes and suspicious cryptitis c/w ulcerative colitis. 3)h/o ethanol use. Formerly drank about 1 six pack/day. 4)cirrhosis. Abd u/s c/w cirrhosis and ascites 5/96. 5)cholelithiasis. By abd u/s. 6)CML. Dx ~1996. Presented with fatigue and weakness. 7)gait instability. Eval recently by neurology c MRI showing prominent basilar artery at the brain stem region, with the appearance of possibly having some thrombosis inside and pressing on the brain stem with compression on one of the pyramids. Likely a fusiform aneurysm with enlargement of the vessel. 8)vasculitis. Manifesting as pruritic R LE lesion responsive to steroids. hydroxyurea 1000 mg per day.

Past Surgical History:  
no bowel or vascular surgeries  
s/p L ACL repair  
s/p tonsillectomy

Family History:

Socio-economic History:  
lives at home c

**DSS**  
**SEP 29 2000**

Allergies: INTERFERON ALFA 2-B

Allergy History:

Physical Exam Latest Vital Signs:

Pulse: 96 supine, 96 seated c legs hanging Blood Pressure: 139/84 supine, 170/97 seated c legs hanging  
Respiratory Rate:12 Temperature: 96.8 pulse ox 98% on RA Pain: 0

General Exam Lying comfortably in bed in no acute distress HEENT EXAM EOMI maxillary dentures op clear and moist NECK EXAM Supple no thyroid enlargement no lymphadenopathy LUNG EXAM Clear to auscultation CARDIOVASCULAR EXAM PMI non-displaced RRR Normal S1 and S2 No murmurs rubs or gallops. ABDOMINAL EXAM Soft Nontender Nondistended No Hepatosplenomegaly No Abnormal Bowel Sounds EXTREMITIES EXAM No edema No cyanosis No clubbing Normal distal pulsations NEURO EXAM A40x3 CN II-XII intact No gross motor or sensory deficits Normal Cerebellar exam on f->n and ram

Radiology: PCXR-> clear lung fields c prominent, tortuous aorta and hilar prominence extending into entire R medial lung field, having a contour c/w

R cardiac silhouette (RA and SVC shadows)

Hospital Course: This 70 yo c known esophageal varices and cirrhosis/portal hypertension, as well as ulcerative colitis was admitted with a suspected upper GI bleed. Two large bore peripheral IVs were started and IVF was administered. He received vitamin K. Immediately following admission to the SICU, the GI service performed an EGD which showed multiple superficial erosions c adherent clot c/w NSAID etiology (daily ibuprofen x 2 weeks), and grade II esophageal varices. No interventions were performed. He was transferred to the floor shortly thereafter, thought to be at low risk for bleeding. He was started on high dose acid suppression. He continued to have nightly loose, melanic stools with his hct drifting down into the high 20s. He was transfused 2units PRBC with a minimal increase in his hct. Thus CBCs were followed bid while on the floor. As his melanic stools lessened he was transfused an additional 1U PRBC with an appropriate increase; the hct stayed at 32 for a reassuring period following transfusion. He was able to ambulate in the halls without any symptoms. An H2 blocker was added to his acid suppression regimen given his relative basophilia (and thus expected relative increased basal level of histamine secretion).

129667

11/99-21

His CML remained stable with his WBC count falling modestly with hydraea. He was d/c when the loose, melanic stools had stopped completely, his coagulopathy had been corrected, and his hct had been stable for 36 hours.

He was to follow up with Dr. [redacted] later in the week and with GI within several weeks.

129667

He agreed to discontinue ibuprofen use. He was offered codeine as an alternative analgesic, but refused it believing he really didn't require anything.

His d/c meds were as on admission with the exception prevacid being added.

His d/c diet was to be as tolerated and his activity ad lib. He was to notify Dr. Auethavekiat should he have any recurrence of melanic stool.

VA COMPETENCY STATUS:

Mr. [redacted] is competent in the VA sense of the word.

THIS ADVERSE DRUG EVENT HAS BEEN DOCUMENTED IN THE PATIENT'S INPATIENT AND OUTPATIENT MEDICATION PROFILES.

ADDENDUM: This case was discussed at the December meeting of the P&T QA Committee. Members said that pt. was 70-year old patient with GI bleeding secondary to ibuprofen. Thirty-six hours prior to admission, patient described loose, dark stools without n/v or abdominal pain. Patient has known esophageal varices and cirrhosis/portal hypertension, as well as ulcerative colitis. The ibuprofen was apparently being given as an OTC medication, since no documentation was found in the hospital computer system that a prescription for it was written here. Ibuprofen was stopped, and EGD was performed to evaluate his GI bleeding. It showed multiple superficial erosions with adherent clot c/w NSAID etiology (daily ibuprofen x 2 weeks), and grade II esophageal varices. No other interventions were performed. The patient was started on high dose gastric acid suppression. The patient continued to have nightly loose, melanic stools with his hematocrit drifting down into the high 20s. After multiple blood transfusions his hematocrit stabilized at about 32. Patient was discharged when the loose, melanic stools had stopped completely, and his hematocrit had been stable for 36 hours. Believe case was handled appropriately.

Section C. Part 10. Concomitant Drugs Continued

- CLOBETASOL PROPIONATE 0.05% OINT
- DM 10/GUAIFENESIN 100MG/5ML SYRUP
- RANITIDINE HCL 150MG TAB
- VITAMIN E 200 UNT CAP
- ABSORBASE TOP OINT
- TRIAMCINOLONE ACETONIDE 0.1% OINT
- ASCORBIC ACID 500MG TAB
- FUROSEMIDE 40MG TAB
- MUPIROCIN 2% OINT
- SPIRONOLACTONE 25MG TAB
- GUAIFENESIN 100MG/5ML SYRUP
- LANSOPRAZOLE CAP, SA
- HYDROXYUREA CAP, ORAL
- ALLOPURINOL TAB



- 11/18/99-11/22/99
- 11/18/99-11/20/99
- 11/18/99-11/18/99

DSS

SEP 29 2000

129667



11/99-21

Dec 28, 1999 11:20 ST LOUIS, MO (CONS)

Pg: 1

129667

Copy- DO NOT PUT IN PATIENT'S CHART

2189

	HA	K	CL	CO2	SEU	BUN	CREAT
12/27/1999 12:02	136	3.8	103	26	92	14	1.0
11/22/1999 04:00	135	3.4L	107H	23L	90	12	0.9
11/20/1999 18:00	133L	3.4L	106H	23L	97	13	0.9
11/20/1999 04:00	135	3.5	108H	21L	74	17	0.8
11/18/1999 08:25	133L	3.7	105	24	102	29H	0.8
11/17/1999 10:48	136	3.3L	104	24	103	26H	0.9
10/26/1999 10:45	134L	4.1	105	25	136H	12	0.9

	WBC	HGB	HCT	PLT	MCV	RBC	MCH
12/27/1999 12:02	67.1H*	12.8L	41L	473H	113H	3.64L	35.2H
12/08/1999 11:11VENOUS	4.7	12L	35.9L	144.L	107.9H	3.33L	36.0H
11/24/1999 10:16	25.6H	11.8L	34.8L	266	104H	3.35L	35.2H
11/22/1999 04:00	74.3H*	10.8L	34.1L	308	108H	3.16L	34.3H
11/21/1999 18:00	93.2H*	11.3L	33.5L	334	108H	3.12L	36.1H
11/21/1999 04:00	102H*	10.8L	31.0L	326	102H	3.04L	35.4H
11/20/1999 18:00	127H*	10.8L	33.5L	342	111H	3.02L	35.6H
11/20/1999 04:00	132H*	9.64L	28.7L	338	111H	2.6L	37.1H
11/19/1999 13:00	145H*	8.6L	28L	371	124H	2.27L	37.9H
11/19/1999 04:00	141H*	8.95L	26.8L	385	115H	2.33L	38.3H
11/18/1999 15:12	157H*	10L	28.6L	418H	111H	2.59L	38.7H
11/18/1999 09:42	159H*	10.4L	31.2L	412H	118H	2.64L	39.2H
11/17/1999 10:48	163H*	11.9L	37.7L	453H	125H	3.01L	39.3H
10/26/1999 10:47VENOUS	13.4H	14	42.8	335.	114.8H	3.73L	37.5H

	SEGS	BANDS	LYM	MONOS	EOSINO	BASO	MACROPH
1999 12:02	comment	"					
12/08/1999 11:11VENOUS	32L	2	10L	41H	9H	6H	
11/24/1999 10:16	67	1L	10L	9H	4H	6H	
11/21/1999 18:00	comment						
11/21/1999 04:00	48L	15H	4L	5	3	5H	
11/20/1999 18:00	comment						
11/19/1999 13:00	47L	18H	4L	10H		5H	
11/18/1999 09:42	47L	14H	3L	6	2	6H	
11/17/1999 10:48	38L	29H	5L	8		2H	
10/26/1999 10:47VENOUS	41	5	15L	20H	2	8H	

DSS  
SEP 29 2000

	RCNT	IRON	FERRIT	TRANSFE	HAPT	B12	FOLATE
11/18/1999 18:00						>2000H	14.6H

	GOT	GPT	AKP	LDH	TBIL	D.BILI	GMMAGT
12/27/1999 12:02	53H		155H		0.9		
11/18/1999 08:25	56H		107		1.0		
11/17/1999 10:48	59H	18	129H		1.0		
10/26/1999 10:45	48H	19	130H	278H	1.3H		

	T.Prot	ALB	CHOL	TRIG	CALCIUM	PO4	U.ACID
12/27/1999 12:02	8.4H	3.4L			9.1		
11/20/1999 18:00					8.1L	3.6	4.3
11/18/1999 08:25	6.7	3.0L			8.5		5.1

129667



\*3582649-1-00-05\*

11/99-24

Dec 28, 1999 11:20 ST LOUIS, MO (CONS)

Pg: 2

for: [REDACTED]

copy- DO NOT PUT IN PATIENT'S CHART

129667

2189 [REDACTED]

	T.Prot	ALB	CHOL	TRIGL	CALCIUM	PO4	U.ACID
11/17/1999 10:48	8.0	3.4L	129	150	8.7		
10/26/1999 10:45	8.1H	3.5	139		9.0		

	PROTIME	PTT	INR	ZTHROMB	BL.TIME	FIBRINO	FDP
11/19/1999 13:00	12.7	26.2	1.13				
11/19/1999 04:00	13.6H	26.5	1.21				
11/18/1999 21:01	14.9H	25.4	1.32				
11/18/1999 15:12	14.3H	24.7	1.27				

	LEU.EST	UR PH	UR PROT	UR GLU	UR KET.	UR BILI	UR BLD.
11/18/1999 16:27URINE	NEG	8.0H	NEG	NEG	NEG	NEG	NEG

	WBC/HPF	RBC/HPF	CASTS	UR CRYST	UR.BACT	UROBILI	Sp.Gr
11/18/1999 16:27URINE						0.2	1.012

DSS

SEP 29 2000

129667



**VOLUNTARY** reporting  
health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31/94  
See OMB statement on reverse

FDA Use Only H Pad  
Trace unit sequence # **130084**

Page CDER of CDER

**A. Patient information**

1. Patient identifier [redacted] In confidence	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
--	--	---	---

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (m/d/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyyy) **8/19/99**

4. Date of this report (m/d/yyyy) \_\_\_\_\_

5. Describe event or problem

*Pt admitted with weakness unresponsive, hypotension and siliphrene air on CXRay. probably from Perfected PUD 20 to NSAID. He was on OTC Motrin for sometimes*

6. Relevant tests/laboratory data, including dates

**RECEIVED**  
OCT 02 2000  
**MEDWATCH CTU**

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

**CTU130084**

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 **MOTRIN**

#2 \_\_\_\_\_

2. Dose, frequency & route used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (month or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for use (indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

**D. Suspect medical device**

1. Brand name \_\_\_\_\_

2. Type of device \_\_\_\_\_

3. Manufacturer name & address \_\_\_\_\_

4. Operator of device  
 health professional  
 lay user/patient  
 other: \_\_\_\_\_

5. Expiration date (m/d/yyyy) \_\_\_\_\_

6. model # \_\_\_\_\_

7. If implanted, give date (m/d/yyyy) \_\_\_\_\_

8. If explanted, give date (m/d/yyyy) \_\_\_\_\_

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

**DSS**

**OCT 03 2000**

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #

**Salisbury VAMC**  
**Salisbury, NC 28144**

2. Health professional?  yes  no

3. Occupation **MD**

4. Also reported to  
 manufacturer  
 user facility  
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: **MEDWATCH**  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

Individual Safety Report



\*3597122-4-00-01\*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



McNeil Consumer Healthcare  
Fort Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

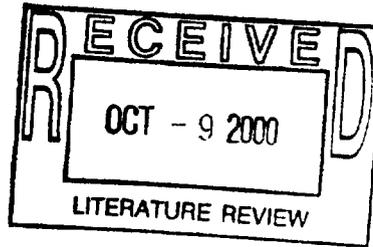
Page \_\_\_\_ of \_\_\_\_

<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient identifier unknown In confidence	2. Age at time of event: 83 yrs Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified OTC ibuprofen product #2 warfarin		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2 unknown dates or duration	
<b>B. Adverse event or product problem</b>				2. Dose, frequency & route used #1 unknown dose, prn, po #2 unknown dose, po		4. Diagnosis for use (indication) #1 joint pain #2 atrial fibrillation	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A		6. Lot # (if known) #1 unknown #2 unknown	
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mo/day/yr) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage (X) other: recovered				7. Exp. date (if known) #1 unknown #2 unknown		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
3. Date of event unknown (mo/day/yr)		4. Date of this report 10/09/00 (mo/day/yr)		9. NDC # - for product problems only (if known) - -			
5. Describe event or problem Literature report (Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 2000;10(4):246-248) of DUODENAL ULCER (multiple small ulcers in antrum & duodenal bulb w/o bleeding) & STOMACH ULCER HEMORRHAGE (ulcer in fundus w/active bleeding) allegedly associated w/use of an unspecified OTC ibuprofen product & warfarin in an 83 yo male. According to report, pt had atrial fibrillation, GERD, & DJD. Pt was taking an unk dose of an unspecified OTC ibuprofen product as needed for joint pains, warfarin, & cimetidine. Pt was admitted to hosp w/ rhabdomyolysis (MYOPATHY) after a cardiac ARRHYTHMIA & a fall (ACCIDENTAL INJURY). On hosp day 4, GI service was consulted & pt was found hypotensive (HYPOTENSION) w/NG tube showing altered blood. Hgb was 5.6g/dL (HYPOCHROMIC ANEMIA) & PT time was 21.2s (PROTHROMBIN INCREASED). Pt rec'd 4U PRBC, 4U FFP, & 1M vitamin K. Hgb did not change significantly, although PT reduced to 15. Urgent upper endoscopy showed large amt of blood in stomach, multiple small ulcers in (See Sect B6)				10. Concomitant medical products and therapy dates (exclude treatment of event) cimetidine 400 mg bid  (Sect B7 cont): Repeat endoscopy 4 wks later showed complete healing of all ulcers.			
6. Relevant tests/laboratory data, including dates on adm:PT=16.4,INR=1.7,Hgb=11.0; hosp day 4:BP=90/50mmHg,Hgb=5.6,PT=21.2,INR=3.1; unk time:PT=15, Hgb=11.1 (Sect B5 cont): antrum & duodenal bulb w/o signs of bleeding. A-6mm ulcer high in fundus w/flat margins & visible (See Sect B7)				<b>G. All manufacturers</b>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) atrial fibrillation, GERD, DJD, no hx of PUD or GI bleeding, nonsmoker, social ETOH use (Sect B6 cont): vessel in its base w/active bleeding. Tx w/1:10,000 epi. Bipolar probe failed. Endoscopic multiband ligator resulted in immediate control of bleeding. Pt started 30 mg bid lansoprazole & given addl 2U PRBC. Hgb increased to 11.1. (See Sect C10)				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303	
				3. Report source (check all that apply) ( ) foreign ( ) study (X) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:		4. Date received by manufacturer (mo/day/yr) 10/09/00	
				5. (A) NDA # 19-012 IND # PLA # pre-1938 ( ) Yes  OTC product (X) Yes		6. Adverse event term(s) ULCER DUODENAL MYOPATHY INJURY ACCID ANEMIA HYPOCHRO ULCER STOMACH H ARRHYTHMIA HYPOTENSION PROTHROMBIN INC	
				6. If IND, protocol #		7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	
				7. Mfr. report number 1441875A		<b>E. Initial reporter</b>	
				1. Name, address & phone # Washington University, VA Medical Center 915 North Grand Boulevard St. Louis, MO 63106		2. Health professional? (X) Yes ( ) No	
				3. Occupation physician		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) No	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

OCT 18 2000  
OCT 17 2000



## Brief Clinical Report

## Endoscopic Band Ligation for Gastric Ulcer Bleeding

Bhaskar Banerjee, MD, Madhuri H. Trivedi, MD, and Abdul M. Swied, MD

**Summary:** Endoscopic band ligation is used commonly to treat variceal bleeding. The use of band ligation has been described in selected cases of nonvariceal bleeding. The successful use of endoscopic band ligation, after the failure of standard techniques, to arrest bleeding in two cases of gastric ulcer hemorrhage is reported. Prospective studies are indicated to further evaluate this technique. **Key Words:** Band—Bleeding—Gastric—Ligation—Ulcer.

Hemorrhage from bleeding peptic ulcers can be managed endoscopically using standard techniques, such as injection of epinephrine and treatment with mono- or multipolar probes or heat probes. Occasionally, active bleeding cannot be controlled successfully by standard endoscopic techniques. We report two such instances in which persistent bleeding from gastric ulcers with visible vessels was controlled easily and immediately by the application of elastic O rings.

## CASE REPORTS

## Case 1

An 83-year-old man was admitted with rhabdomyolysis after a cardiac arrhythmia and a fall. He had atrial fibrillation, gastroesophageal reflux disease, and degenerative joint disease. He was taking warfarin (prothrombin time, 16.4 sec; international normalized ratio, 1.7), cimetidine (400 mg twice daily), and nonprescription ibuprofen as needed for joint pains. There was no history of peptic ulcer disease or gastrointestinal bleeding. The patient was a nonsmoker who drank alcohol socially. The

gastroenterology service was consulted on the fourth day of hospitalization when the patient was found to be hypotensive (blood pressure, 90/50 mm Hg), with a nasogastric tube showing altered blood. His hemoglobin concentration was 5.6 g/dL (11.0 g/dL at admission) and prothrombin time was 21.2 seconds (international normalized ratio, 3.1). Four units of packed red blood cells and four units of fresh frozen plasma were transfused, and intramuscular vitamin K was administered. The patient's hemoglobin concentration did not change significantly, although his prothrombin time was reduced to 15 seconds. An urgent upper endoscopy showed a large amount of blood in the stomach. Multiple small ulcers were seen in the antrum and duodenal bulb without any signs of bleeding. With a retroflexed view of the stomach, a 6-mm diameter ulcer was seen high in the fundus, with flat margins and a visible vessel in its base, with active bleeding. Using a 7-French, 240-cm needle catheter (Wiltech Medical, Winston-Salem, NC, USA), a total of 8 mL of 1:10,000 epinephrine was injected at the margins and center of the ulcer base. Blanching was noted after injection, but the ulcer continued to bleed actively. A 7-French, 400-cm bipolar probe (Pentax, Orangeburg, NJ, USA) was used to try to arrest the bleeding, but this also failed. An endoscopic multiband ligator (Wilson-Cook Medical; Winston-Salem, NC, USA) was then used. Suction was applied at the ulcer base, with the bleeding point at the center. The ulcer was easily suctioned into the suction cup attached to the endoscope tip, and a single elastic O ring was released using the stan-

Received October 18, 1999; revision received March 29, 2000; accepted April 8, 2000.

From the Division of Gastroenterology (BB), Washington University School of Medicine, St. Louis, Missouri, USA; and the Division of Gastroenterology (MT, AS), University of Missouri-Columbia, Columbia, Missouri, USA.

Address correspondence to Bhaskar Banerjee, MD, Division of Gastroenterology, Washington University, VA Medical Center (111/JC), 915 North Grand Boulevard, St. Louis, MO 63106, USA.



standard technique (1). There was immediate control of bleeding from the ulcer site, and the entire ulcer bed appeared to have been ligated. Thirty milligrams oral lansoprazole twice daily was started. The patient was administered another two units of packed red blood cells, and his hemoglobin concentration increased to 11.1 g/dL, without any further decrease. Endoscopy repeated 4 weeks later showed complete healing of all ulcers, including the one that was ligated; the fundic ulcer site was completely healed, without any visible scar or impression of the elastic O ring site.

#### Case 2

A 73-year-old man was transferred from another hospital, where he had been admitted for 1 day with melena and a hemoglobin concentration of 9.8 g/dL. Intravenous infusion of ranitidine was begun, and endoscopic evaluation at the referring hospital had revealed a gastric ulcer with active bleeding. No endoscopic treatment was performed. The patient had a history of hypertension, atrial fibrillation, cerebrovascular accident, chronic obstructive pulmonary disease, peripheral vascular disease, and rheumatoid arthritis. In the past, he had had a cholecystectomy, repair of an abdominal aortic aneurysm, and a right above-knee amputation. He was taking warfarin (prothrombin time, 14.8 seconds; international normalized ratio, 1.2), 750 mg salsalate three times daily, and 60 mg diltiazem three times daily. Examination on admission to this hospital showed stable vital signs, a soft nontender abdomen, and no signs of active bleeding. Soon after admission to our hospital, melena developed, and the patient's hemoglobin concentration was 7.8 g/dL. The patient was started on intramuscular vitamin K, administered a transfusion of two units of packed red blood cells and four units of fresh frozen plasma, which increased his hemoglobin concentration to 9.6 g/dL and normalized his prothrombin time. He remained hemodynamically stable. An urgent endoscopy revealed fresh blood in the stomach, with a 6-mm-diameter gastric ulcer located just below the gastroesophageal junction. There was active bleeding with a prominent visible vessel. Using a 7-French, 240-cm needle catheter (Wiltech Medical), a total of 12 mL of 1:10000 epinephrine was injected around and into the ulcer bed; however, rapid bleeding continued. The endoscopic multiband ligator (Wilson-Cook Medical) was attached to the endoscope. The ulcerated area was easily suctioned into the suction cup of the multiband ligator, and a single O ring was applied around the visible vessel using the same technique as used for patient 1. There was immediate arrest of bleeding. The patient remained stable. The patient was

treated with 30 mg lansoprazole daily, and a repeat endoscopy 6 weeks later showed complete ulcer healing.

#### DISCUSSION

Gastrointestinal bleeding is a common medical emergency; peptic ulcer disease accounts for approximately 50% of all cases (1). The mortality rate of bleeding peptic ulcers is 6% to 12% (2). Epidemiologic data indicate that the use of nonsteroidal antiinflammatory drugs is an important risk factor for bleeding in peptic ulcer (3). Anticoagulant therapy also increases the risk of a bleeding ulcer developing, with a relative risk of 3.3 (3). A combination of nonsteroidal antiinflammatory drugs and anticoagulation, as in both our patients, increased the risk of bleeding. Rapid correction of coagulopathy is vital for such patients. Currently used endoscopic hemostatic methods for bleeding peptic ulcers include thermal methods (mono- and multipolar electrocoagulation), heater probe, injection therapy using epinephrine, hypertonic solutions and sclerosants, and use of metallic clips (1). Endoscopic band ligation for control of variceal bleeding (4) has steadily gained popularity as a result of its safety, effectiveness, and ease of use. The first description of endoscopic band ligation to control bleeding from an ulcer after injection and bipolar probe coagulation had failed was in 1991 (5). The technique has been used to treat bleeding varices outside the esophagus and stomach (6), postpolypectomy bleeding (7,8), Dieulafoy lesion (9,10), and angiodysplasia (9,11). Wong et al. (9) reported the successful use of this technique in 12 patients with gastroduodenal bleeding: 4 with a Dieulafoy lesion, 3 with duodenal ulcer, 2 with gastric angiodysplasia, and 3 with Mallory-Weiss tears. They selectively treated lesions that were superficial and nonfibrotic and suggested that this technique would be unsuitable for treating large fibrotic ulcers. The ulcer beds in both our patients were small and nonindurated, which facilitated elastic band application. A large ulcer with an indurated fibrotic base would be very difficult to suction into the suction cup of the endoscopic ligator before releasing the elastic O ring. This is supported by published reports of successful band ligation that was limited to small nonindurated lesions (7-11). In both of our patients, use of a single elastic O ring across the ulcer caused immediate cessation of bleeding, with stabilization of hemoglobin and hematocrit concentrations, after traditional endoscopic techniques had failed. In each case, care was taken to apply the bands directly over the site of the visible vessels. After failure of injection therapy in the second patient, band ligation was attempted without trying other coagulating devices because of continued rapid blood loss and



difficulty maintaining, for an extended period, the position of the endoscope just below the gastroesophageal junction. Without band ligation, active bleeding might have continued, and surgical intervention, although undesirable in such patients, would have been the only alternative. Endoscopic hemostasis by band ligation is believed to cause mechanical strangulation of the bleeding vessel, followed by thrombosis and fibrosis, therefore making it a suitable method for patients with coagulopathy. The technique is simple and immediately arrested the bleeding in both patients. Prospective randomized studies should be performed to assess the safety and effectiveness of this therapy for gastrointestinal hemorrhage and to define lesions that are most suitable for this technique.

#### REFERENCES

1. Laine L. Acute and chronic gastrointestinal bleeding. In Feldman M, Scharschmidt BE, Sleisenger MH, eds. *Gastrointestinal and Liver disease: Pathophysiology/Diagnosis/Management*. Philadelphia: WB Saunders, 1997:198-219.
2. Longstreth GF. Epidemiology of hospitalization for acute upper gastrointestinal hemorrhage: a population-based study. *Am J Gastroenterol* 1995;90:206-10.
3. Shore BI, Ray WA, Daugherty JR, Griffin MR. Concurrent use of nonsteroidal anti-inflammatory drugs and oral anticoagulants places elderly persons at high risk for hemorrhagic peptic ulcer disease. *Arch Intern Med* 1993;153:1665-70.
4. Steigmann GV, Cambre T, Sun JH. A new endoscopic band ligation device. *Gastrointest Endosc* 1986;32:230-3.
5. Tseng C, Burke S, Connors P, Green R, Carr-Locke DL. Endoscopic band ligation for treatment of non-variceal upper gastrointestinal bleeding. *Endoscopy* 1991;23:297-8.
6. Levine J, Tahiri A, Banerjee B. Endoscopic ligation of bleeding rectal varices. *Gastrointest Endosc* 1993;39:188-90.
7. Smith RE, Douli J. Treatment of colonic post-polypectomy bleeding site by endoscopic band ligation. *Gastrointest Endosc* 1994;40:499-500.
8. Slivka A, Parson WG, Carr-Locke DL. Endoscopic band ligation for treatment of post-polypectomy hemorrhage. *Gastrointest Endosc* 1994;40:230-2.
9. Wong R, Ota S, Katoh A. Endoscopic ligation for non-esophageal variceal upper GI hemorrhage. *Endoscopy* 1998;30:774-7.
10. Brown GR, Harford WV, Jones WF. Endoscopic band ligation of an actively bleeding Dieulafoy's lesion. *Gastrointest Endosc* 1994;40:501-3.
11. Campo R, Brullet E. Endoscopic treatment of gastric angiodysplasia with elastic band ligation. *Gastrointest Endosc* 1996;43:502-4.