

Safety Reports

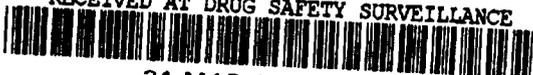
OTC NSAID: Naproxen

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 Naproxen

All Case Reports Submitted on GI Bleeding reported in association with OTC Naproxen (89) reported for January 1998 - December 2001.



31-MAR-1998-0924

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY report by health professionals of events and product prob.

Individual Safety Report



3062082-1-00

Page ___ of ___

A. Patient information

1. Patient identifier 68155 In confidence	2. Age at time of event: 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): 07-1996

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

5. Describe event or problem

hematochezia,
hypotension,
tachycardia

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/labeled, if known)

#1 Naprosyn

#2

2. Dose, frequency & route used

#1

#2

3. Therapy dates (if unknown, give duration)

#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)

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

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)

80380

E. Reporter (see confidentiality section on back)

1. Name (please print)

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

A. Patient information

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

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	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: <u>peritonitis</u>

3. Date of event (mo/day/yr) 04/02/98	4. Date of this report (mo/day/yr) 04/08/98
--	--

5. Describe event or problem
 HCP reported a leak in the drain bag of the Ultrabag set for home patient. HCP states that patient had developed peritonitis around March 19th. Patient was treated with Vancomycin 2 gm. IP x 14 days however, peritonitis did not resolve. HCP states catheter was pulled on 4/2/98 and patient is temporarily on hemodialysis until infection is resolved. No permanent injury has been incurred by patient as per HCP.

8. Relevant tests/laboratory data, including dates
 4/2/98-Culture of effluent=gram neg rods, pseudomonas

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

MAILED ON:
 APR 10 1998
BY: [redacted]

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.

APR 14 1998

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 UltraBag Low Calcium PD Solution with 2.5 mEq/L of Calcium -- 509766 #2 _____	
2. Dose, frequency & route used #1 Dose=1.5 liters Frequency=daily Route=IP #2 _____	3. Therapy dates (if unknown, give duration) #1 Unknown #2 _____
4. Diagnosis for use (indication) #1 ESRD #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) #1 C381689 #2 _____	7. Exp. date (if known) #1 08/31/99 #2 _____
9. NDC # - for product problems only (if known) <u>Unk</u>	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) NA	

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: _____ (specify)
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mo/day/yr) 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 # [redacted] Kidney Center [redacted] St. [redacted]		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation R.N.	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk



14-APR-1998-0002

Baxter Healthcare Corporation

Experience Report (continued)

Refer to FDA guidelines for specific instructions

submit
an address
facility,
city,
state,
zip
Page

Individual Safety Report



3063700-4-00

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 (m/day/yr)		7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # ___	8. Date of this report (m/day/yr)
9. Approximate age of device	10. Event problem codes (refer to coding manual)		
	patient code	<input type="text"/>	<input type="text"/>
	device code	<input type="text"/>	<input type="text"/>
11. Report sent to FDA? <input type="checkbox"/> yes (m/day/yr) <input type="checkbox"/> no		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient <input type="checkbox"/> home <input type="checkbox"/> diagnostic facility <input type="checkbox"/> nursing home <input type="checkbox"/> ambulatory <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> surgical facility <input type="checkbox"/> other: _____ specify	
13. Report sent to manufacturer? <input type="checkbox"/> yes (m/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 (m/day/yr)	
6. Evaluation codes (refer to coding manual)		5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no	
method	<input type="text"/>	<input type="text"/>	<input type="text"/>
results	<input type="text"/>	<input type="text"/>	<input type="text"/>
conclusions	<input type="text"/>	<input type="text"/>	<input type="text"/>
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 Noemi Romero-Kondos Baxter Healthcare Corp 1 Baxter Parkway Deerfield, IL 60015		2. Phone number 847-948-3796	
4. Date received by manufacturer (m/day/yr) 04/08/98		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: _____ specify	
6. If IND, protocol # NA		5. (A)NDA #20-183 IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
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 type="checkbox"/> initial <input type="checkbox"/> follow-up #: _____		8. Adverse event term(s) Peritonitis	
9. Mfr. report number 198040808-C381599-01			

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 the burden, to Washington, DC 20503

Report 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.

APR 14 1998

RECEIVED AT DRUG SAFETY SURVEILLANCE



14-APR-1998-0003

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015-4833

847.948.2000
Fax: 847.948.3948

Baxter

Individual Safety Report
3063700-4-00

April 10, 1998

Food and Drug Administration
Central Document Room
Park Building, Room 214
12420 Parklawn Drive
Rockville, MD 20857

Re: 15-Day "Alert Report"

Reference NDA 20-183: Dianeal® Peritoneal Dialysis Solution in Ultrabag™

To Whom It May Concern:

Pursuant to 21 CFR 314.80, Baxter Healthcare Corporation, Renal Division, is submitting the attached Adverse Reaction Report (FDA Form 3500A).

This will constitute a final report concerning this event, unless additional significant information becomes available. If you have any questions, I may be reached by telephone at (847) 948-3796.

Sincerely,

Noemi Romero-Kondos, RN, BSN
Manager, Product Surveillance
Renal Division

Enclosure

APR 14 1998



01-APR-1998-0955

VOLUNTARY health professionals of events and product pro

Individual Safety Report



3065089-3-00

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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 checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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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 4/11/95 (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) 4/7/95

4. Date of this report (mo/day/yr) 3/25/98

5. Describe event or problem

patient was admitted to the hospital for perforated duodenal ulcer and perforated viscus. she underwent surgery but died 4 days later

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 Naproxen

#2 prednisone

2. Dose, frequency & route used

#1 ?

#2 1

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

#1 ?

#2 1

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.

APR 0 1 1998

4. Operator of device

health professional

lay user/patient

other.

5. Expiration date (mo/day/yr)

6. MEDWATCH CTU

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], Pharm. D.
[Redacted] medical center
[Redacted] St

2. Health professional? yes no

3. Occupation Pharmacist

4. Also reported to

manufacturer

user facility

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

distributor



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9778

or FAX to:
1-800-FDA-0178

80499



28-APR-1998-1430

APPENDIX

NTARY reporti
ssionals of adve
product problem:

Individual Safety Report
3072042-2-00

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier 042466 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
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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/yr) 01-1997

4. Date of this report (month/yr) 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 Naprosyn

#2 _____

2. Dose, frequency & route used

#1 _____

#2 _____

3. Therapy dates (if unknown, give duration)

#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)

82012

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/yr)

6. model #

7. # implanted, give date (month/yr)

8. # explanted, give date (month/yr)

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

yes no returned to manufacturer on _____ (month/yr)

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone

J. 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

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.



3072066-5-00

RECEIVED AT DRUG SAFETY SURVEILLANCE

VOLUNTARY reporting professionals of adverse and product problems

CDER

PDA Use Only (AHFS) See OMB statement on reverse

Trace unit sequence # 81969



28-APR-1998-1485

30 of

A. Patient information

1. Patient identifier: 103117. 2. Age at time of event: In confidence. 3. Sex: female/male. 4. Weight: lbs/kgs.

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, other.

3. Date of event: 04-1997. 4. Date of this report: 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 & mfr/labeler, if known): Naprosyn. 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 and therapy dates.

D. Suspect medical device

1. Brand name. 2. Type of device. 3. Manufacturer name & address. 4. Operator of device. 5. Expiration date. 6. model #, catalog #, serial #, lot #, other #. 7. If implanted, give date. 8. If explanted, give date. 9. Device available for evaluation? 10. Concomitant medical products and therapy dates.

E. Reporter (see confidentiality section on back)

1. Name, address, phone: [Redacted], Ph.D., FASCP, Hospital, P.O. Box, Phone [Redacted]

2. Health professional? 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 1008 MEDWATCH CTU



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



28-APR-1998-1511



3072153-1-00

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

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CDER

PDA Use Only (AMS)

Trace and sequence # **81958**

Page ___ of ___

A. Patient information

1. Patient identifier 149588 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
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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 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) **07-1997**

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

5. Describe event or problem

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 Naprosyn	
#2 _____	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) (m/d/y to last estimate)
#1 _____	#1 _____
#2 _____	#2 _____
4. Diagnosis for use (indication)	
#1 _____	
#2 _____	
5. Event abated after use stopped or dose reduced	6. Event reappeared after reintroduction
#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#1 <input 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	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
7. 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 (m/day/yr)	
6. If implanted, give date (m/day/yr)	
7. If explanted, give date (m/day/yr)	
8. 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/day/yr)	
9. 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? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation pharmacist	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 type="checkbox"/>			



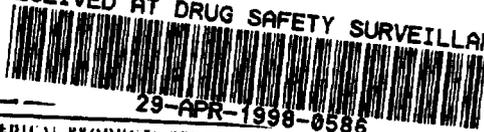
Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

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.

RECEIVED AT DRUG SAFETY SURVEILLANCE



29-APR-1998-0586

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report



3678832-4-00

ARY report
ionals of adv
duct problem

COM

82054

A. Patient information

1. Patient identifier 281221	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: **10-1995**

4. Date of this report: **03-1998**

5. Describe event or problem
Acute. GI Bleeding

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 **Naprosyn / ASA**

#2 _____

2. Dose, frequency & route used

#1 _____

#2 _____

3. Therapy dates (if unknown, give duration)

#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.

APR 29 1998

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (m/d/yyyy)

6. Model #

MEDWATCH GTU

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)

82054

E. Reporter (see confidentiality section on back)

1. Name, address, telephone

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

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



22-MAY-1998-0555

7031 SENT DATE: 05/15/1998

se by user-facil
s and manufac
DATORY re|

e 1 of 1



3082922-X-00

FDA Use Only

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: 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. <input checked="" type="checkbox"/> 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) UNKNOWN	4. Date of this report (mo/day/yr) 05/14/1998

5. Describe event or problem
A CONSUMER REPORTED, VIA MERCK RESEARCH LABORATORIES, DEVELOPING AN ESOPHAGUS PROBLEM FROM TAKING MOTRIN AND NAPROSYN. IT WAS REPORTED THAT SHE SUBSEQUENTLY DEVELOPED A BLEEDING ULCER, AND WAS HOSPITALIZED. TREATMENT AND OUTCOME INFORMATION WERE NOT PROVIDED.

8. Relevant tests/laboratory data, including dates
NO DATA PROVIDED

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
OSTEOPOROSIS; UNSPECIFIED PAIN; SPURS ON HER SPINE;

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 MOTRIN Tablets	
#2 NAPROSYN	
2. Dose, frequency & route used	3. Therapy dates (if unk, give duration)
#1 ORAL	#1 UNKNOWN
#2 UNKNOWN	#2 UNKNOWN
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a UNK
#2 PAIN	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a UNK
6. Lot # (if known)	7. Exp. date (if known)
#1 UNKNOWN	#1 UNKNOWN
#2 UNKNOWN	#2 UNKNOWN
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a UNK	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a UNK	
9. NDC # - for product problems only (if known) UNKNOWN	
10. Concomitant medical products and therapy dates (exclude treatment of event) PREMARTIN CALCIUM	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
RODNEY F. CARLSON, M.D., DIRECTOR CORP. PHARMACOVIGILANCE-KALAMAZOO PHARMACIA & UPJOHN COMPANY 7000 PORTAGE ROAD KALAMAZOO, MICHIGAN 49001	(616) 833-8777
4. Date received by mfr (mo/day/yr) 05/12/1998	3. Report source (check all that apply)
6. If IND, protocol #	<input type="checkbox"/> foreign
7. Type of report (check all that apply)	<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	<input checked="" type="checkbox"/> consumer
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #	<input type="checkbox"/> health professional
5. (A)NDA # 17463	<input type="checkbox"/> user facility
IND #	<input checked="" type="checkbox"/> company representative
PLA #	<input type="checkbox"/> distributor
pre-1938 <input type="checkbox"/> Yes	<input type="checkbox"/> other:
OTC product <input type="checkbox"/> Yes	
8. Adverse event term(s)	
9. Mfr. report number	BLEEDING ULCER; ESOPHAGUS PROBLEM FROM MOTRIN AND NAPROSYN
5312/17463	

E. Initial reporter

1. Name, address & phone # PATIENT REPORT			
MAY 26 1998			
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	



05-JUN-1998-2910

For VOLUNTARY reporting
by health professions of adv
events and product proble
CDER

Individual Safety Report



3091301-0-00

41657

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier: 980150023
 2. Age at time of event: 80
 3. Sex: female male
 4. Weight: 105 lbs or 48 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 date 2-19-98
 life-threatening
 hospitalization - initial or prolonged

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

3. Date of event: 1/15/98
 4. Date of this report: 5/27/98

72/10 massive GI bleed (naprosyn, ASA) 80 year old male nursing home patient transferred here 1/15 with hypotension, hematemesis and admitted through the ER. Past medical history includes COPD, arthritis, heart disease. His nursing home medications included theophylline, aspirin, clonidine, furosemide, Cardizem, naprosyn, ampicillin. There was no history of GI bleed. He had bright red blood per NG tube and was hypotensive. IV fluids were started. Hematocrit reported at 1955 as 30.2 and at 0030 24.5. Chemistries revealed azotemia. Emergent EGD 1/15; repeat 1/16, arterial embolization with contrast media done 1/16. Hematocrit continued to decrease, acidosis worsened. Exploratory lap for bleeding gastric ulcer 1/16 found 750-1000cc clot in stomach, arterial oozing. Pathology report: Benign gastric ulcer, chronic superficial gastritis, active, no evidence of malignancy, negative for Helicobacter pylori. Postoperative hematocrit 24%, orders for vitamin K, DDAVP, platelets. He now had lateral gaze but was hemodynamically stable. Neuro found bilateral infarcts on CT scan - left MCA infarct. 1/18: he was awake, on ventilator, nods in response, but does not follow commands. There was no focal weakness. EEG showed severe encephalopathy. Creatinine continuing to rise (3.4) but urine output was adequate. He continued to receive platelets, vitamin K. INR was 1.4. Ventilator weaning began 1/20 with T-piece. 1/22 trach to be placed; hematocrit 32; blood products continued. 1/24: Urine output decreasing (I/O +3000ml). DVT noted right upper extremity. Dialysis began 1/25. 1/26 at 21:15: dehiscence of abdominal incision with evisceration. Emergent reexploration for debridement fascia, reclosure, I&D. Drainage of subphrenic abscess and wound closure. DVT better. GI bleeding has stopped (some incision bleeding); now anuric; hematocrit 25.7, CT shows multiple infarcts; poor prognosis for functional recovery; continued dialysis; continued hematology support. 1/30 patient is now "no Harvey Team". 2/12 He continued to have bleeding from nose, tracheal aspirate. NGT, vas cath site and continued to require hematology support 2/13 more GI bleeding with coffee ground material from NGT. 2/16: persistent factor VII deficiency in spite of ample vitamin K supplementation consistent with hepatocellular defect -- now septic, still on dialysis, ventilator, new upper GI bleed. Expired 2/19 of respiratory failure. Conclusion: probable 4

REC'D.

JUN 05 1998

MEDWATCH CTU

C. Suspect medication(s)

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

2. Dose, frequency & route used
 #1 oral
 #2 oral

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
 #1 To 1/15/98
 #2 To 1/15/98

4. Diagnosis for use (indication)
 #1 Arthritis
 #2 heart disease

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)
 #1 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)
Theophylline Clonidine Lasix
Cardizem Ampicillin

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 #

 _____ Hosp. Dept. Pharmacy
 _____ Avenue

2. Health professional?
 yes no

3. Occupation
 Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

FDA

To FDA

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report



CDEK

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 56
Date of birth: [redacted]

3. Sex: female male

4. Weight: ND 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 disability
 life-threatening congenital anomaly
 hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage
 other:

3. Date of event (month/year): 10-1-98

4. Date of this report (month/year): 10-8-98

5. Describe event or problem:
 Patient on SWOG 9300/9007 w/ C6L on Hydrea since 12-16-97, on ATRA since 1-27-98 admitted 10-1-98 for GI bleeding probably 2° to hemorrhagic gastritis 2° to Naprosyn. Rule out bleeding peptic ulcer. Patient had persistent bloody stools. Transfusion of 3 units of blood. D/C on chromagen 10-4-98. Patient is expected to recover fully. This event appears to be unrelated to the study drug.

6. Relevant tests/laboratory data, including dates:
 37.6 WBC } 10-1-98
 8.2 HGB }
 26.4 HCT }

7. Other relevant history, including preexisting conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, renal/hepatic dysfunction, etc.):
 C6L
 OCT 09 1998
 MEDWATCH CTU
 (First notification to Clin Res. Office 10-8-98)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known):
 #1 NAPROSYN
 #2

2. Dose, frequency & route used:
 #1 UNKNOWN, PO
 #2

3. Therapy dates (if unknown, give duration) (month/year):
 #1
 #2

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

5. Event started 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):
 HYDREA 1000 mg qd
 ATRA 70 mg qd.

D. Suspect medical device

1. Brand name: [redacted]

2. Type of device: [redacted]

3. Manufacturer name & address: [redacted]

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

5. Expiration date (month/year): [redacted]

6. Model # [redacted]

7. If repaired, give date (month/year): [redacted]

8. If replaced, give date (month/year): [redacted]

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

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:
 [redacted] ST.
 [redacted]
 [redacted] MED & LTR.

2. Health professional? yes no

3. Occupation: CLINICAL RES. MGR

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, 5800 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (4/97)

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



HF-2

CTU 90748



Individual Safety Report



3144367-3-00-01

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

FDA Use Only

Triage unit sequence # 91350

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

CDE

A. Patient information

1. Patient identifier 98-51 In confidence	2. Age at time of event: or Date of birth: 52	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 (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) 6/8/98

4. Date of this report (mo/day/yr) 10/1/98

5. Describe event or problem

6/6/98 ↑ abdominal pain, Bury stool + vomit w blood

DIAG:
acute upper GI bleed

6. Relevant tests/laboratory data, including dates

REC'D.

OCT 21 1998

MEDWATCH CTU

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

Hx depression Hgb 14.5

Chronic back pain WBC 11,200

- ETOH

- smoke

C. Suspect medication(s)

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

#1 Naprosyn

#2

2. Dose, frequency & route used

#1 N/A

#2

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

#1 5/27/98 - 6/8/98

#2

4. Diagnosis for use (indication)

#1 chronic 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 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)

Zoloft 50mg, Vicodin, Robaxin

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]

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.

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

CTU 91350

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

CDER



3144807-X-00-01

ADR Report for FDA: 4Q97 - 2Q98

[Redacted] Hospital - [Redacted] Region, [Redacted] Road, [Redacted]

Med Rec #: [Redacted] Age: 075 Sex: F Rxn Date: 5/30/98

ADR: GI BLEED

Medication: NAPROXEN

Probability: 3 2 = Possible 3 = Probable 4 = Definite

Route: PO

Comments:

Diagnosis: GI BLEED

Pat. Outcome: 1 1 = Resolved/No Sequelae 2 = Cont. Treatment 3 = Perm. Disability 4 = Incr. L.O.S. 5 = Death

REC'D.

OCT 13 1998

MEDWATCH: CTU

CTU
90867

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM
Individual Safety Report



3160633-X-00-01

Triage unit sequence #

92904

A. Patient Information

1. Patient Identifier [REDACTED] 2. DOB: [REDACTED] 3. Sex: MALE 4. Weight: 89.4 kg
AGE: 79 yrs

B. Adverse Event or Product Problem

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

3. Date of event: 10/26/98 4. Date of this report: 11/02/98

5. Describe event or problem
GI BLEED

6. Relevant test/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions

C. Suspect Medication(s)

1. Name
#1: NAPROXEN

2. Dose, frequency & route used #1:
3. Therapy dates #1:

4. Diagnosis for use (indication) #1:
5. Event abated after use stopped or dose reduced? #1: [N/A]

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

9. (Not applicable to adverse drug event reports)

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

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]

2. Health professional? [YES] 3. Occupation: PHYSICIAN 4. Reported to MFR [NO]

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

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

or FAX to:
1-800-FDA-0178

CTA 92904



04-MAY-1998-1959

Use by user-facilities, distributors and manufacturers for mandatory report

Approved by the FDA on: Sept 17 1997

Individual Safety Report



3165230-8-00-01

A. Patient information

1. Patient Identifier	2. Age at time of event: or 84 YEARS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight or _____ lbs _____ 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"/> 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"/> other: MEDICALLY SIGNIFICANT
3. Date of event _____ mo _____ day _____ yr	4. Date of this report MAY 1 1998 mo day yr

5. Describe event or problem
 AN 84-YEAR-OLD FEMALE CONSUMER EXPERIENCED BLEEDING GASTRIC ULCER AND STOMACH EROSIONS DURING THE USE OF NAPROSYN (NAPROXEN) FOR AN UNKNOWN INDICATION.
 1988: NAPROSYN WAS STARTED, DOSAGE AND ROUTE UNKNOWN.
 DATE UNKNOWN: THE CONSUMER EXPERIENCED BLEEDING GASTRIC ULCER AND STOMACH EROSIONS.
 1994: NAPROSYN WAS STOPPED.
 AT THE TIME OF REPORT 18 SEP 97, THE CONDITION OF THE CONSUMER WAS UNKNOWN.

C. Suspect medication(s)

1. Name & Strength (give mfr/labeler, if known) #1 NAPROSYN (NAPROXEN) #2	
2. Dose, frequency & route #1 UNKNOWN #2	3. Therapy dates (if unk. give duration) from/to or best estimate #1 15-JUN-1988 E/15-JUN-1994 E #2
4. Diagnosis for use (indication) #1 UNKNOWN #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) #1 #2	7. Exp. date #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) #1 #2	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

G. All manufacturers

1. Contact Office-name/address (& mfring site for devices) Global Development Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110-1199	2. Phone Number (973) 562-3523
4. Date received by manufacturer SEP 18 1997 mo day yr	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 checked="" type="checkbox"/> other: OTHER
5. (A)NDA # 17-581 IND # PLA # pre-1938 OTC product <input type="checkbox"/> yes <input type="checkbox"/> no	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 #	8. Adverse event term(s) BLEEDING GASTRIC ULCER EROSIONS IN STOMACH
9. Mfr. report number 86933	

E. Initial reporter

1. Name, address & phone # [REDACTED] STREET UNITED STATES OF AMERICA		
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.



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

15

MAY 04 1998



04-MAY-1998-1962

Use by user-facilities, stores and mandatory

Individual Safety Report

Approved by the FDA on: Case 17-1000



3165240-0-00-01

A. Patient information			
1. Patient Identifier	2. Age at time of event: or 62 YEARS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight or _____ lbs _____ 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"/> 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 _____ _____ 1997 E	4. Date of this report MAY 1 1998		
5. Describe event or problem			
A 62-YEAR-OLD FEMALE PATIENT WAS HOSPITALISED DUE TO PEPTIC ULCER DISEASE, PANCYTOPENIA AND CONGESTIVE HEART FAILURE DURING THE USE OF ORAL NAPROSYN (NAPROXEN) AND LOZOL (INDAPAMIDE) FOR UNSPECIFIED INDICATIONS AND REZULIN (TROGLITAZONE) FOR TYPE I DIABETES.			
THE PATIENT HAS A HISTORY OF SJOJREN'S SYNDROME FOR 15 YEARS, ANAEMIA, LEUKOPENIA OF UNKNOWN ORIGIN AND HYPOTHYROIDISM FOR 30 YEARS.			
1994/5: START OF LOZOL AND NAPROSYN, DOSAGE UNKNOWN.			
1997: START OF REZULIN, ROUTE AND DOSAGE UNKNOWN.			
THE PATIENT EXPERIENCED A THREE WEEK HISTORY			
Continued			
6. Relevant tests/laboratory data, including dates			
ESOPHAGOGASTRODUODENOSCOPY			
1997 E			
Continued			
7. Other relevant history			
VERBATIM MEDICAL HISTORY TERM(S):			
SJOJREN'S SYNDROME			
FIBROMYALGIA			
DEPRESSION			
ANAEMIA			
Continued			

C. Suspect medication(s)		
1. Name & Strength (give mfr/labeler, if known)		
#1 NAPROSYN (NAPROXEN)		
#2 REZULIN (TROGLITAZONE)		
2. Dose, frequency & route		3. Therapy dates (if unk. give duration from/to or best estimate)
#1 ORAL		#1 15-JUN-1994 E /
#2 UNKNOWN		#2 15-JUN-1997 E / CONTINUING
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 DIABETES HELLITUS TYPE 1		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date	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 (if known)		
#1		
#2		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
ARTIFICIAL TEARS (ARTIFICIAL TEARS) / CONTINUING		
CYCLOBENZAPRINE (CYCLOBENZAPRINE HYDROCHLORIDE) / CONTINUING		
EUCERIN CREAM (UNSCENTED MOISTURIZING FORMULA) / CONTINUING		
Continued		
G. All manufacturers		
1. Contact Office-name/address (& mfring site for devices)		2. Phone Number (973) 562-3523
Global Development Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110-1199		3. Report source (check all that apply)
4. Date received by manufacturer OCT 31 1997		<input type="checkbox"/> foreign
5. (A)NDA # 17-581		<input type="checkbox"/> study
IND #		<input type="checkbox"/> literature
PLA #		<input type="checkbox"/> consumer
pre-1938 OTC product <input type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> health professional
6. If IND, protocol #		<input type="checkbox"/> user facility
7. Type of report (check all that apply)		<input checked="" type="checkbox"/> company representative
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day		<input type="checkbox"/> distributor
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic		<input type="checkbox"/> other:
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #		
8. Adverse event term(s)		
PEPTIC ULCER DISEASE		
PANCYTOPENIA		
CONGESTIVE HEART FAILURE		
- OEDEMA		
- WEIGHT GAIN		
- DYSPNOEA		
(- denotes comanifestation)		
9. Mfr. report number		
89457		

E. Initial reporter		
1. Name, address & phone #		
[REDACTED]		
[REDACTED] AVERUE		
UNITED STATES OF AMERICA		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	M. D.	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk.

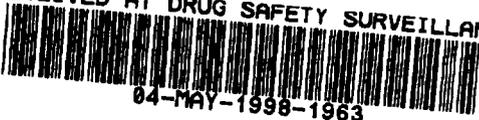


Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

'E' INDICATES ESTIMATED DATE
'P' INDICATES PARTIAL DATE

MAY 04 1998

18



04-MAY-1998-1963

Mfr. report num



3165240-0-00-02

B. 5 - Describe Event or Problem - Continued

OF RETAINING FLUIDS AND DIFFICULTY BREATHING, WITH PAROXYSMAL NOCTURNAL DYSPNOEA AND ORTHOPNOEA. SHE WAS HOSPITALISED WITH FOCUS ON FLUID OVERLOAD. SHE ALSO EXPERIENCED HIGH OUTPUT CONGESTIVE HEART FAILURE SECONDARY TO ANAEMIA, PANCYTOPENIA AND PEPTIC ULCER DISEASE. COAGULATION AND BIOCHEMISTRY TESTS WERE NORMAL. ESOPHAGOGASTRODUODENOSCOPY SHOWED MULTIPLE BLEEDING ULCERS BUT BIOPSY WAS NEGATIVE FOR HELICOBACTER PYLORI. URINALYSIS WAS NEGATIVE. ECG SHOWED NORMAL LEFT VENTRICULAR SIZE AND FUNCTION WITH POSTERIOR HYPOKINESIA, NORMAL SINUS RHYTHM WITH PAROXYSMAL SUPRAVENTRICULAR CONTRACTION AND LEFT AXIS DEVIATION. IRON STUDIES SHOWED IRON DEFICIENCY. ELECTROPHORESIS AND IMMUNOFIXATION TESTS RULED OUT MALIGNANCY. PAROXYSMAL NOCTURNAL HAEMOGLOBINURIA WAS ALSO RULED OUT.

NAPROSYN AND LOZOL WERE STOPPED. REZULIN WAS CONTINUED.

22 JUL 97: THE PATIENT WAS TREATED WITH IV LASIX (FUROSEMIDE) AND THE PATIENT DIURESED 4.5 LITRES. THE OEDEMA OF HER LOWER LEGS DECREASED SLIGHTLY.

23 JUL 97: BONE MARROW BIOPSY SHOWED VARIABLY CELLULAR BONE MARROW WITH MEGALOBLASTOID ERYTHROPOIESIS, DECREASED NUMBER OF MEGAKARYOCYTES, DECREASED IRON STORES AND WAS NEGATIVE FOR FUNGUS AND ACID-FAST BACILLI.

DATE UNK: THE DYSPNOEA AND ORTHOPNOEA RESOLVED. ALL OTHER SYMPTOMS IMPROVED AFTER TREATMENT WITH 2 UNITS OF PACKED RED BLOOD CELLS AND THE PATIENT WAS DISCHARGED.

B. 6 - Relevant Tests & Laboratory Data - Continued

LAB TEXT:

MULTIPLE BLEEDING ULCERS. NEGATIVE FOR HELICOBACTER PYLORI.

COAGULATION_TEST

DATE: 1997 E

LAB TEXT:

NORMAL

OTHER_CHEM_RESULTS

DATE: 1997 E

LAB TEXT:

BIOCHEMISTRY NORMAL

ECG

DATE: 1997 E

LAB TEXT:

NORMAL LEFT VENTRICULAR SIZE AND FUNCTION WITH POSTERIOR HYPOKINESIA, NORMAL SINUS RHYTHM WITH PAROXYMAL SUPRAVENTRICULAR CONTRACTION AND LEFT AXIS DEVIATION.

URINALYSIS

DATE: 1997 E

LAB TEXT:

NEGATIVE

BONE MARROW BIOPSY

DATE: 23-JUL-1997

LAB TEXT:

VARIABLY CELLULAR BONE MARROW WITH MEGALOBLASTOID ERYTHROPOIESIS, DECREASED NUMBER OF MEGAKARYOCYTES, DECREASED IRON STORES, NEGATIVE FOR FUNGUS AND ACID-FAST BACILLI.

ELECTROPHORESIS

DATE: 1997 E

LAB TEXT:

RULED OUT MALIGNANCY.

IMMUNOFIXATION_ELECT

DATE: 1997 E

LAB TEXT:

RULED OUT MALIGNANCY.

B. 7 - Other Relevant History - Continued

LEUKOPENIA

ADENOMA

MAY 04 1998

19

LIVER BIOPSY
HYPOTHYROIDISM
TYPE I DIABETES

C. 1thru. C.8 - Suspect Medication(s) continued:

LOZOL (INDAPAMIDE)
EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: YES
EVENT REAPPEARED AFTER REINTRODUCTION: DOESN'T APPLY
Therapy Dates: 15-JUN-1994 E /
DOSE/FRCNCY/ROUTE: UNKNOWN INDICATION: UNKNOWN

C. 10 - Concomitant Medication and Therapy Dates - Continued

FERROUS SULFATE / CONTINUING
(FERROUS SULFATE)
FOSAMAX / CONTINUING
(ALENDRONATE SODIUM)
HUMALOG / CONTINUING
(INSULIN LISPRO)
NPH INSULIN / CONTINUING
(INSULIN (SUSPENSION), ISOPHANE)
PEPCID / CONTINUING
(FAMOTIDINE)
PROZAC / CONTINUING
(FLUOXETINE)
SYNTHROID / CONTINUING
(LEVOthyroxine SODIUM)
TYLENOL / CONTINUING
(ACETAMINOPHEN)
VITAMIN C / CONTINUING
(ASCORBIC ACID)



RECEIVED AT DRUG SAFETY SURVEILLANCE



MAY 04 1998

20

Individual Safety Report



VOLUNTARY reporting
alth professionals of adverse
nts and product problems



Form Approved: OMB No. 0918-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit
sequence # 97403

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 11

A. Patient information

1. Patient Identifier [redacted] In confidence
2. Age at time of event: 89
3. Sex: female
4. Weight: [redacted] lbs

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 (m/d/yy)
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:
3. Date of event (m/d/yy): 11-12-98
4. Date of this report (m/d/yy): 2-11-99

5. Describe event or problem
Adm 11-12 Fecal occult blood (+)
INR = 5.09
BP 104/59 HR = 101
vet K 10mg IM x 1
FFP x 2
PRBC x 1 } 11-12
GI consult - GI bleed 2^o Naprosyn, ASA + warfarin
Pt discharged 11-16

6. Relevant tests/laboratory data, including dates
H/H = 11.2/33.3 11-14
INR = 8.09 11-12
H/H 9.2/27.0 11-12

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



C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ASA (3) warfarin
#2 Naprosyn
2. Dose, frequency & route used
#1 unknown
#2
3. Therapy dates (if unknown, give duration) (month for best estimate)
#1 RTA
#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)
-
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/yy)
6. model # FED 11 1999
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
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] Hospitals
[redacted] SS
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.

PLEASE TYPE OR USE BLACK INK



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 97403



MEDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report #	8-98184-001M
UF/Dist report #	
FDA Use Only	

A. Patient Information

1. Patient identifier [REDACTED]	2. Age at time of event: 21 YR or Date of birth: Unknown	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 110 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 (mo/day/yr)	<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"/> recovered	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 11 / 00 / 97

4. Date of this report (mo/day/yr) 07 / 03 / 98

5. Describe event or problem

Information has been received from a 21-year-old female consumer who had taken Duract for "a few weeks" in 11/97 for a bruised rib. Concomitant therapy was not provided. Medical history included Vicodan (hydrocodone bitartrate and acetaminophen), Motrin (ibuprofen) and Naprosyn (naproxen) use prior to Duract therapy (dates unknown) and carrier of Alpha 1 Antitrypsin deficiency. The patient developed a GASTROINTESTINAL BLEED a couple of weeks following Duract therapy. She was hospitalized for 6 days and discharged on Prevacid (lansoprazole) which she took for approximately 3 months. She experienced a second gastrointestinal bleed in 3/98 (details not provided). Additional information has been requested.

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.)

Vicodan, Motrin and Naprosyn use prior to Duract therapy; carrier of Alpha 1 Antitrypsin deficiency.

DATE SENT TO FDA
09 / 14 / 98

FDA Form 3500A (facsimile) 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 DURACT

#2 MOTRIN (IBUPROFEN)

2. Dose, frequency & route used

#1 1 capsule daily ORAL

#2 Unknown

3. Therapy dates (if unknown, give duration)

#1 11 / 00 / 97 to Unknown

#2 Unknown

4. Diagnosis for use (indication)

#1 BRUISED RIB

#2 Unknown

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)

Unknown

G. All manufacturers

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

WYETH-AYERST LABORATORIES
170 RADNOR CHESTER ROAD
ST. DAVIDS, PA. 19087

KAREL F. BERNADY, PH.D.

2. Phone number (610) 902-3760

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) 06 / 30 / 98

5. (A)NDA # 20-535

IND #

PLA #

pre-1938 yes

OTC product yes

6. Adverse event term(s)

GASTROINTESTINAL HEMORRHAGE

7. Type of report (check all that apply)

5-day 15-day
 10-day periodic
 initial follow-up #

8. Mfr. report number

8-98184-001M

E. Initial reporter

1. Name, address & phone #

[REDACTED]
[REDACTED] Road
[REDACTED]

2. Health professional? yes no

3. Occupation N/A

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

SEP 15 1998
25

WYETH-/
170 RAD/
- DAVII



TS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report #	8-98184-001W
UF/Dist report #	
FDA Use Only	

C. Suspect medication(s)

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

SEP 15 1998

Individual Safety Report



3241328-0-00-01

5 LOPC

Approved by FDA on 10/20/93

CDEF

Triage unit sequence #

101285

Page 1 of 1

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight
[REDACTED] | AGE: 71 yrs | MALE | 0.0

C. Suspect Medication(s)

1. Name
#1: NAPROXEN

B. Adverse Event or Product Problem

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

2. Dose, frequency & route used | 3. Therapy dates
#1: | #1:

4. Diagnosis for use (indication) | 5. Event abated after use
#1: | #1: [N/A]
stopped or dose reduced?

3. Date of event | 4. Date of this report
03/12/99 | 03/19/99

DSS

5. Describe event or problem
GI BLEED

APR 19 1999

ADVERSE EVENT REPORTING SYSTEM

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

10. Concomitant medical products/therapy dates (exclude treatment)
DIGOXIN 0.25MG TAB
SIMVASTATIN 5MG TAB
TERAZOSIN 2MG CAP
PLEASE SEE ATTACHED

7. Other relevant History, including preexisting medical conditions

PT ON CHRONIC COUMADIN THERAPY. PT GIVEN RX FOR NAPROXEN FOR ARTHRITIS PAIN AND WAS TOLD BY PCP TO TAKE 250MG QD TO BID HOWEVER PT TOOK NAPROXEN 500MG BID AND PRESENTED TO CLINIC WITH COMPLAINTS OF WEAKNESS AND RECTAL BLEEDING. LABS 3/12/99 INR 3.6 H/H 8/25. PT WAS ADMITTED TO LOCAL

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], BCPS
VAMC AMARILLO 6010 AMARILLO BLVD WEST
AMARILLO, TEXAS 79106 [REDACTED]

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.

CTU 101285

Individual Safety Report



3241328-0-00-02

101285

SPECT MEDICATION: NAPROXEN

DATE OF EVENT: 3/12/99

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

TEST: oINR-L RESULTS: 3.6 COLLECTION DATE: 3/12/99@12:28
 TEST: oPROTIME-L RESULTS: 22.8 COLLECTION DATE: 3/12/99@12:28
 TEST: WBC-L RESULTS: 9.6 K/cumm H:10.8/L:4.8 COLLECTION DATE: 3/12/99@12:28
 TEST: RBC-L RESULTS: L 2.76 M/cumm H:6.1/L:4.2 COLLECTION DATE: 3/12/99@12:28
 TEST: HGB-L RESULTS: L 8.7 G/dL H:15/L:12 COLLECTION DATE: 3/12/99@12:28
 TEST: oHCT-L RESULTS: L 25.3 % H:52/L:37 COLLECTION DATE: 3/12/99@12:28
 TEST: oMCV-L RESULTS: 91.6 fL H:99/L:80 COLLECTION DATE: 3/12/99@12:28
 TEST: oMCH-L RESULTS: 31.5 pg H:33/L:27 COLLECTION DATE: 3/12/99@12:28
 TEST: oMCHC-L RESULTS: 34.3 g/dL H:36/L:31 COLLECTION DATE: 3/12/99@12:28
 TEST: oRDW-L RESULTS: 13 % H:14.5/L:11.5 COLLECTION DATE: 3/12/99@12:28
 TEST: oPLT-L RESULTS: 161 K/cumm H:400/L:140 COLLECTION DATE: 3/12/99@12:28
 TEST: oMPV-L RESULTS: 9.6 fL H:10.4/L:7.4 COLLECTION DATE: 3/12/99@12:28
 TEST: oEDIFF RESULTS: ELECTRONIC DIFFERENTIAL COLLECTION DATE: 3/12/99@12:28
 TEST: oNEUT %-L RESULTS: H 81.3 % H:73/L:37 COLLECTION DATE: 3/12/99@12:28
 TEST: oLYMPH %-L RESULTS: L 11.7 % H:40/L:20 COLLECTION DATE: 3/12/99@12:28
 TEST: oMONO %-L RESULTS: 5.6 % H:12/L:0 COLLECTION DATE: 3/12/99@12:28
 TEST: oEO %-L RESULTS: 0.4 % H:10/L:0 COLLECTION DATE: 3/12/99@12:28
 TEST: oBASO %-L RESULTS: 1.0 % H:3/L:0 COLLECTION DATE: 3/12/99@12:28
 TEST: oNEUT #-L RESULTS: H 7.9 K/cumm H:6.5/L:1.4 COLLECTION DATE: 3/12/99@12:28
 TEST: oLYMPH #-L RESULTS: 1.1 K/cumm H:3.6/L:1 COLLECTION DATE: 3/12/99@12:28
 TEST: oMONO #-L RESULTS: 0.5 K/cumm H:.7/L:0 COLLECTION DATE: 3/12/99@12:28
 TEST: oEO #-L RESULTS: 0.0 K/cumm H:.3/L:.1 COLLECTION DATE: 3/12/99@12:28
 TEST: oBASO #-L RESULTS: 0.1 % H:3/L:0 COLLECTION DATE: 3/12/99@12:28
 TEST: oLUBBOCK LAB RESULTS: "LUBBOCK LABORATORY" COLLECTION DATE: 3/12/99@12:28

Section C. Part 10. Concomitant Drugs Continued

METHOCARBAMOL 500MG TAB
 NAPROXEN 250MG TAB
 TOCOPHEROL 400U CAP
 ASPIRIN 81MG CHEWABLE TAB
 THERAPEUTIC FORM VITAMIN W/MINERALS TAB
 WARFARIN SODIUM 5MG TAB
 CARBIDOPA 25MG/LEVODOPA 100MG TAB
 FLUOXETINE (PROZAC) 20MG CAP
 ACETAMINOPHEN 300MG/CODEINE 30MG TAB
 DIPHENHYDRAMINE 50MG CAP
 CLONAZEPAM 1MG TAB
 CAPSAICIN 0.025% CR, (PER GM)

DSS

APR 19 1999

ADVERSE EVENT REPORTING SYSTEM

CTU 101285



VOLUNTARY reporting health professionals of adverse events and product problems CDER



Form Approved: OMB No. 0910-0231 Expires: 4/30/98 See OMB statement on reverse FD-1085 (Use Only) FD-1085 (Use Only) 102452

A. Patient information

1. Patient identifier [redacted] 2. Age at time of event: 78 Years 3. Sex: [] female [x] male 4. Weight: [] lb [] kg

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 [] life-threatening [x] hospitalization - initial or prolonged [] disability [] congenital anomaly [] required intervention to prevent permanent impairment/damage [] other:

3. Date of event 3/12/1999 4. Date of this report 05/04/1999

5. Describe event or problem (up to a total of 6400 characters allowed) Upper GI Bleed Patient was coughing up blood. DSS MAY 07 1999 ADVERSE EVENT REPORTING SYSTEM

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) Admitted for by-pass (fem-pop) MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING SYSTEM HF-2

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Naprosyn #2 Ketoprofen 2. Dose/Frequency/Route used #1 #2 3. Therapy dates (if unknown, give duration) #1 3/12/1999 - #2 3/12/1999 - 4. Diagnosis for use (separate indications with commas) #1 arthritis #2 arthritis 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) - - 10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

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 # REC'D. 7. If implanted, give date MAY 07 1999 8. If explanted, give date MEDWATCH CTU

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

10. Concomitant medical products and therapy dates (up to a total of 1000 characters) Patient was also taking aspirin.

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone [redacted] Address [redacted] Hospital Department of Pharmacy [redacted] Street [redacted] E-mail (for electronic acknowledgement)

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

CTU 102452

Individual Safety Report



3261533-7-00-01

user-facilities,
manufacturers for
DRY reporting.

APPROVED BY FDA ON 03/06/98

Mfr report #	98664
UF/Dist. report #	
FDA Use only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information

1. Patient identifier [REDACTED]	2. Age at time of event: or 70 YEARS Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 195.1 lbs or 88.5 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)

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

3. Date of event (m/d/yr) / / 1996 E

4. Date of this report (m/d/yr) MAY / 10 / 1999

5. Describe event or problem

A 70-YEAR-OLD MALE PATIENT DEVELOPED WORSENING OF PEPTIC ULCER SYMPTOMS DURING THE USE OF NAPROSYN (NAPROXEN) FOR OSTEOARTHRITIS.

THE PATIENT HAD A HISTORY OF OCCASIONAL FLARE UP OF GASTRIC ULCERS (SINCE 1983) WITH SYMPTOMS OF NAUSEA AND SEVERE PAIN, AND HAD EXPERIENCED DEPRESSION. HE HAD NO KNOWN ALLERGIES AND HAD QUIT BOTH ALCOHOL CONSUMPTION (1978) AND SMOKING (1996).

1990: ORAL NAPROSYN WAS STARTED FOR OSTEOARTHRITIS IN THE FINGERS, KNEES AND LOWER BACK.

1996: THE PATIENT EXPERIENCED INCREASED FREQUENCY OF GASTRIC ULCER FLARE UP. THIS WAS RELIEVED WITH TAGAMET (CIMETIDINE).

JUL 97: THE PATIENT'S SYMPTOMS WORSENERD AND WERE DESCRIBED AS A GENERAL DISCOMFORT WITH FEELINGS OF MALAISE BUT NO PAIN. THESE SYMPTOMS WERE DIFFERENT TO THE PATIENT'S PREVIOUSLY REPORTED ULCER PROBLEMS. NO STOOL BLOOD WAS NOTED. SYMPTOMS DID NOT IMPROVE DESPITE TREATMENT WITH TAGAMET.

CONTINUED

6. Relevant tests/laboratory data, including dates

UNK

RECEIVED
MAY 11 1999
BY: _____

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

Medical History Terms
GASTRIC ULCER
DEPRESSION

Medical History Text
THE PATIENT EXPERIENCED OCCASIONAL FLARE UP OF GASTRIC ULCERS SINCE 1983 WITH SYMPTOMS OF

CONTINUED

C. Suspect medication(s)

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

#1 NAPROSYN (NAPROXEN)

#2 NA

2. Dose, frequency & route

#1 ORAL

#2 NA

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

#1 15-JUN-1990 E / 15-OCT-1997 E

#2 NA

4. Diagnosis for use (indication)

#1 OSTEOARTHRITIS

#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 UNK

#2 NA

7. Exp. date (if known)

#1 UNK

#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)

#1 NA #2 NA

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

CYTOTEC 15-JUN-1990 E / CONTINUING (MISOPROSTOL)

PROZAC 15-JUN-1996 E / CONTINUING

CONTINUED

G. All manufacturers

1. Contact Office-name/address

GLOBAL DEVELOPMENT
HOFFMANN-LA ROCHE INC.
340 KINGSLAND STREET
NUTLEY, NJ 07110-1199

2. Phone Number

(973) 562-3523

3. Report source (check all that apply)

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

4. Date received by manufacturer

APR / 28 / 1998

5. (A)NDA# 17-581

IND # _____
PLA # _____
pre-1938 yes
OTC yes
product yes

6. If IND, protocol #

NA

7. Type of report (check all that apply)

5-day 15-day
 10-day periodic
 initial follow-up # _____

8. Adverse event term(s)

WORSENING OF PEPTIC ULCER SYMPTOMS +++
-GASTRITIS HEMORRHAGIC
-DUODENITIS
-DISCOMFORT

9. MFR. report number

98664

+++ adverse event that generated submission
-comanifestation

E. Initial reporter

1. Name, address & phone #

JANET JARAMILLA
SEARLE
4901 SEARLE PARKWAY
SKOKIE ILLINOIS 50077
UNITED STATES OF AMERICA

CONTINUED

2. Health professional?

yes no

3. Occupation

PHARMACIST

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.

E-Indicates estimated date, P-Indicates partial date

B.5. Describe event or problem - continued

OCT 97: THE PATIENT WAS DIAGNOSED WITH HAEMORRHAGIC GASTRITIS AND DUODENITIS. NAPROSYN WAS DISCONTINUED AND THE PATIENT WAS STARTED ON TREATMENT WITH BIAXIN (CLARITHROMYCIN) FOR 2 WEEKS, PRILOSEC (OMEPRAZOLE), DAYPRO (OXAPROZIN) AND INCREASED DOSAGE CYTOTEC (MISOPROSTOL) 200 MCG, BID.

29 APR 98: THE PATIENT REPORTED THAT HIS ULCER HAD IMPROVED, BUT STILL OCCASIONALLY FLARED UP ON DRINKING COFFEE, MILK, ORANGE JUICE OR TEA. HE HAS TRIED TO AVOID THESE LIQUIDS.

THE COMPANY CONSIDERED THE EVENT AS MEDICALLY SIGNIFICANT. NO ADDITIONAL INFORMATION WAS PROVIDED.

B.7. Other relevant history - continued

NASUEA AND SEVERE PAIN.
HE QUIT SMOKING IN 1996 AND QUIT ALCOHOL CONSUMPTION IN 1978.
THE PATIENT HAD NO KNOWN ALLERGIES.

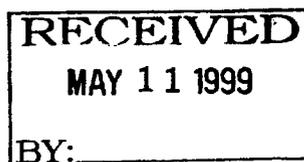
C.10. Concomitant medical products and Therapy Dates - continued

(FLUOXETINE HYDROCHLORIDE)

TAGAMET 15-JUN-1996 E / CONTINUING
(CIMETIDINE)

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: 847-982-7055



Individual Safety Report



3261538-6-00-01

For use by user-facilities,
and manufacturers for
ADVERSE reporting.

APPROVED BY FDA ON 03/06/98

Mfr report #	102839
UF/Dist. report #	
FDA Use only	

1 of 2

A. Patient information

1. Patient Identifier [REDACTED]	2. Age at time of event: 61 YEARS or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 225.1 lbs or 102.1 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)

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

3. Date of event (mo/day/yr) DEC / 20 / 1997	4. Date of this report (mo/day/yr) MAY / 10 / 1999
---	---

5. Describe event or problem

A FEMALE CONSUMER OF UNKNOWN AGE WAS HOSPITALISED DUE TO HAEMORRHAGIC OESOPHAGEAL ULCER DURING/FOLLOWING THE USE OF NAPROSYN (NAPROXEN) FOR AN UNSPECIFIED INDICATION.

THE CONSUMER HAD A MEDICAL HISTORY OF OSTEOPOROSIS, PAIN AND SPINE SPURS. UNKNOWN DATE: NAPROSYN AND MOTRIN (IBUPROFEN) WAS STARTED (DOSAGES, ROUTES AND FREQUENCIES NOT SPECIFIED). THE PATIENT WAS HOSPITALISED WITH A BLEEDING ULCER.

NO ADDITIONAL INFORMATION WAS PROVIDED.

FURTHER INFORMATION RECEIVED ON 20 JUL 98 INDICATED THAT:
THE CONSUMER IS 61 YEARS OLD WITH A HISTORY OF BARRETT'S METAPLASIA WHICH CAN LEAD TO CANCER, HIGH BLOOD PRESSURE AND ELEVATED CHOLESTEROL LEVELS.
DATE UNKNOWN: NAPROSYN WAS STARTED FOR PAIN CAUSED BY OSTEOPOROSIS.
20 DEC 97: THE PATIENT WAS HOSPITALISED FOR BLEEDING ULCER IN HER OESOPHAGUS. SHE WAS GIVEN

CONTINUED

6. Relevant tests/laboratory data, including dates

HEMOGLOBIN
20-DEC-1997
LOW.

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

Medical History Terms
OSTEOPOROSIS
BARRETT'S SYNDROME
HIGH BLOOD PRESSURE
ELEVATED CHOLESTEROL

Medical History Text

RECEIVED

MAY 11 1999

BY: _____

CONTINUED

C. Suspect medication(s)

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

#1 NAPROSYN (NAPROXEN)

#2 MOTRIN (IBUPROFEN)

2. Dose, frequency & route

#1 ORAL

#2 UNK

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

#1 UNK

#2 UNK

4. Diagnosis for use (indication)

#1 PAIN

#2 UNKNOWN

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 (if known)

#1 NA #2 NA

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

PREMARIN UNK (ESTROGENS, CONJUGATED)

CALCIUM UNK

CONTINUED

G. All manufacturers

1. Contact Office-name/address

GLOBAL DEVELOPMENT
HOFFMANN-LA ROCHE INC.
340 KINGSLAND STREET
NUTLEY, NJ 07110-1199

2. Phone Number
(973) 562-3523

3. Report source (check all that apply)

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

4. Date received by manufacturer
JUL / 20 / 1998

5. (A)NDA# 17-581
IND # _____
PLA # _____
pre-1938 yes
OTC yes
product

6. If IND, protocol #
NA

7. Type of report (check all that apply)

5 - day 15 - day
 10 - day periodic
 initial follow-up # _____

8. Adverse event term(s)
HEMORRHAGIC ESOPHAGEAL ULCER +++
-DECREASED HEMOGLOBIN

9. MFR. report number
102839

+++ adverse event that generated submission -comanifestation

E. Initial reporter

1. Name, address & phone #

[REDACTED] AVENUE
UNITED STATES OF AMERICA

2. Health professional?
 yes no

3. Occupation
UNK

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.

B.5. Describe event or problem - continued

A BLOOD TRANSFUSION BECAUSE HER HAEMOGLOBIN LEVEL WAS LOW, CAUSED BY THE BLEEDING.
25 DEC 97: THE PATIENT WAS DISCHARGED FROM HOSPITAL. THE ULCERS HEALED AND THE BLEEDING RESOLVED.

B.7. Other relevant history - continued

THE CONSUMER HAD A MEDICAL HISTORY OF SPURS ON HER SPINE.

C.10. Concomitant medical products and Therapy Dates - continued

(CALCIUM NOS)

ATENOLOL UNK
(ATENOLOL)

PRAVACHOL UNK
(PRAVASTATIN SODIUM)

PRINZIDE UNK
(HYDROCHLOROTHIAZIDE/LISINOPRIL)

ELAVIL UNK
(AMITRIPTYLINE HYDROCHLORIDE)

Individual Safety Report



3261538-6-00-02

RECEIVED
MAY 11 1999
BY: _____

Individual Safety Report



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

use by user-facilities,
hospitals and manufacturers for
MANDATORY reporting.

APPROVED BY FDA ON 03/06/98

MFR report #	111722
UF/Dist. report #	
FDA Use only	

Page 1 of 2

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or _____ 40 YEARS 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. <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"/> disability
<input type="checkbox"/> life threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization initial or prolong	<input type="checkbox"/> required intervention to prevent
	<input type="checkbox"/> permanent impairment/damage
	<input type="checkbox"/> other:
3. Date of event / / 1996 E	4. Date of this report MAY / 10 / 1999

5. Describe event or problem

A 40 YEAR OLD MALE PATIENT WAS HOSPITALISED WITH A DUODENAL ULCER DURING THE USE OF NAPROSYN (NAPROXEN) FOR BACK PAIN.

THE PATIENT HAD A HISTORY OF ULCERS IN 1972 AND HAD SURGERY ON ONE MEASURING 3 CM. HE HAD RECEIVED MOTRIN (IBUPROFEN) THERAPY IN 1993, AND 1995.

1996 (APPROX.): THE PATIENT COMMENCED NAPROSYN THERAPY (DOSE, ROUTE AND REGIMEN UNSPECIFIED). 4 DAYS LATER: HE EXPERIENCED A DUODENAL ULCER AND WAS ADMITTED TO HOSPITAL. THE PATIENT TESTED POSITIVE FOR H. PYLORI. HE RECEIVED ULCER SURGERY.

6 DAYS LATER: THE PATIENT WAS DISCHARGED FROM HOSPITAL.

AT THE TIME OF THE REPORT, 6 JAN 99, THE PATIENT WAS IN GOOD HEALTH.

THE REPORTER WAS THE PATIENT'S PHYSICIAN'S LAWYER.

6. Relevant tests/laboratory data, including dates
CULTURE_RESULTS 1996 E H. PYLORI POSITIVE.
<div style="border: 2px solid black; padding: 5px; width: fit-content; margin: auto;"> <p>RECEIVED</p> <p>MAY 11 1999</p> <p>BY: _____</p> </div>

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

Medical History Terms
ULCER
ULCER SURGERY

Medical History Text
1972: THE PATIENT HAD A HISTORY OF ULCERS.
1993 AND 1995: THE PATIENT RECEIVED MOTRIN

CONTINUED

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 NAPROSYN (NAPROXEN)	
#2 NA	
2. Dose, frequency & route	3. Therapy dates (if unk. give duration) from/to (or best estimate)
#1 ORAL	#1 15-JUN-1996 E / 15-JUN-1996 E
#2 NA	#2 NA
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 BACK PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" 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 UNK	#1 UNK
#2 NA	#2 NA
9. NDC # for product problems only (if known)	8. Event reappeared after reintroduction
#1 NA #2 NA	#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)	
FLEXERIL CONTINUING (CYCLOBENZAPRINE HYDROCHLORIDE)	

G. All manufacturers

1. Contact Office-name/address	2. Phone Number
GLOBAL DEVELOPMENT HOFFMANN-LA ROCHE INC. 340 KINGSLAND STREET NUTLEY, NJ 07110-1199	(973) 562-3523
4. Date received by manufacturer	3. Report source (check all that apply)
JAN / 6 / 1999	<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user-facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input checked="" type="checkbox"/> other: LAWYER
6. If IND, protocol #	5. (A)NDA#
NA	17-581
7. Type of report (check all that apply)	IND # _____
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	PLA # _____
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic	pre-1938 <input type="checkbox"/> yes
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	OTC product <input type="checkbox"/> yes
9. MFR. report number	8. Adverse event term(s)
111722	DUODENAL ULCER +++
	+++ adverse event that generated submission

E. Initial reporter

1. Name, address & phone #
DRIVE UNITED STATES OF AMERICA

CONTINUED



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

E-Indicates estimated date, P-Indicates partial date

B.7. Other relevant history - continued

THERAPY.

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: [REDACTED]

Individual Safety Report



3261542-8-00-02

RECEIVED
MAY 11 1999
BY: _____

Individual Safety Report



#3262665-X-00-01*

CDER CDW
CDER
Page 1 of 2

Approved by FDA on 10/20/93

Triage unit sequence #

102874

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight
[REDACTED] | AGE: 51 yrs | MALE | 58.7 kg

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

3. Date of event | 4. Date of this report
03/11/99 | 05/04/99

5. Describe event or problem
GI BLEED

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

7. Other relevant History, including preexisting medical conditions

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

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.

C. Suspect Medication(s)

1. Name
#1 : NAPROSYN

2. Dose, frequency & route used | 3. Therapy dates
#1: | #1 :

4. Diagnosis for use (indication) | 5. Event abated after use
#1: | #1: [N/A]
stopped or dose reduced?

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

9. (Not applicable to adverse drug event reports)

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

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 #: PHARMACY SERVICE
1201 N W 16TH STREET
MIAMI, FLORIDA 33125 324-4455

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]



REC'D.

MAY 14 1999

MEDWATCH CTU

DSS

MAY 17 1999

ADVERSE EVENT REPORTING SYSTEM

CTU 102874

COED

page 2 of 2

102874

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: NAPROSYN

DATE OF EVENT: 3/11/99

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

TEST: HGB RESULTS: L* 4.4 g/dL H:17.2/L:12.8 COLLECTION DATE: 3/10/99@17:03

TEST: HCT RESULTS: L* 14.8 % H:48.2/L:40.2 COLLECTION DATE: 3/10/99@17:03

TEST: HGB RESULTS: 13.3 g/dL H:17.2/L:12.8 COLLECTION DATE: 9/15/98@10:24

TEST: HCT RESULTS: L 39.1 % H:48.2/L:40.2 COLLECTION DATE: 9/15/98@10:24

Individual Safety Report



3262665-X-00-02

MEDICAL
RECORDS

HF-2

DSS

MAY 17 1999

ADVERSE EVENT REPORTING SYSTEM

102874



The FDA Medical Products Reporting Program

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

Triage Unit Sequence #

103825

Page 1 of 1



CDER

SYSTEM ELECTRONIC 3500 FORM ADAPTATION, Version 1.01, September 1997

A. Patient Information

1. Patient Identifier [REDACTED] 1700 (In confidence)	2. Age at time of event: or Date of birth: [REDACTED]	3. Sex F	4. Weight [REDACTED] lbs 0 kgs
---	---	-------------	--------------------------------------

B. Adverse Event or Product Problem

1. Adverse Event and/or Product Problem

2. Outcomes attributed to adverse event

<input type="checkbox"/> Death	<input type="checkbox"/> Disability
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital anomaly
<input checked="" type="checkbox"/> Hospitalization - initial	<input type="checkbox"/> Required intervention to prevent permanent impairment/damage
<input type="checkbox"/> Hospitalization - prolonged	

3. Date of event (mo/day/yr) [REDACTED]

4. Date of this report (mo/day/yr) 6/1/99

5. Describe event or problem

A pharmacist reported that a patient began receiving an unspecified regimen of naproxen on an unspecified date for an unspecified indication. On an unspecified date the patient presented to the emergency care center with GASTROINTESTINAL BLEEDING, GASTROINTESTINAL ULCERATION, HEMATEMESIS, HEMATOCHESIA, and ANEMIA. The patient was ADMITTED TO THE HOSPITAL, where naproxen was discontinued. Additional treatment included vitamin K (intravenous and oral), platelets, fresh frozen plasma, packed red blood cells, and an endoscopy. The reaction was reported to have resolved.

REC'D.

JUN 02 1999

MEDWATCH CTU

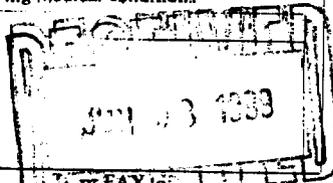
6. Relevant tests/laboratory data, including dates

Serum Creatinine: 0.6

None noted

7. Other relevant history, including preexisting medical conditions

Allergies: NKDA
peptic ulcer disease



FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville MD 20852
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

C. Suspect Medication(s)

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

#1	naproxen
#2	

2. Dose, frequency, route used

#1	
#2	

3. Therapy Dates (from/to)

#1	
#2	

4. Diagnosis for use (indication)

#1	
#2	

5. Event abated after use stopped or dose reduced

#1	Yes
#2	

6. Lot # (if known)

#1	
#2	

7. Exp. date

#1	
#2	

8. Event reappeared after reintroduction

#1	Unknown
#2	

9. NDC # (for product problems only)

#1	
#2	

10. Concomitant medical products

D. Suspect Medical Device

These fields not used for electronic 3500 reporting at [REDACTED]

Internal ADR Event Coding

Reaction 1:	gastrointestinal bleeding
Reaction 2:	anemia
Reaction 3:	gastrointestinal ulceration
Reaction 4:	hematemesis
Reaction 5:	hematochezia

E. Reporter (see confidentiality section on back)

1. Name, address and phone #

ADR Program Coordinator / Drug Information Service
Department of Pharmacy and Drug Information
[REDACTED] Box [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 03828

3309028-6-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

ARM. RES. INST. USA
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999002540
UP/Dist report #
FDA Use Only

A. Patient information			
1. Patient identifier ? - ?	2. Age at time of event: 39 yr	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 59 lbs
*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. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death ??/??/?? (mo/day/yr) <input type="checkbox"/> life-threatening <input checked="" 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 (mo/day/yr) ??/??/??	4. Date of this report (mo/day/yr) 07/19/99		
5. Describe event or problem			
Report published in 1998 Annual Report of Poison Control Centers Toxic Exposure Surveillance System (case 658) of a 39-year-old (sex unspecified) who committed suicide by ingesting acetaminophen with codeine, carisoprodol, and naproxen (doses, date unspecified). Blood concentration acetaminophen 6 mcg/mL. Chronicity was acute for carisoprodol. Additional information received 08-Jul-99: A 39-year-old female (weight 59 kg) was found on the floor unconscious by her boyfriend after a poly drug overdose. It was unknown how long the patient had been unconscious following the ingestion of an unknown amount of carisoprodol, acetaminophen with codeine and naproxen. The patient presented to a rural hospital in coma, where she had been given orogastric lavage and activated charcoal. She presented to a referral hospital with a heart rate of 141, blood pressure 117/96, respiratory rate of 14, temperature 36.5 C, and mental status which was described as agitated but confused. Her O2 saturation was 96% on 4 liters of oxygen. Initial laboratory evaluation included the (Cont.)			
6. Relevant tests/laboratory data, including dates			
Blood concentration acetaminophen 6 mcg/mL Additional information received 08-Jul-99: heart rate 141, blood pressure 117/96, respiratory rate 14, temperature 36.5 C, O2 saturation was 96% on 4 liters of oxygen, sodium 129, potassium 6.4, chloride 90, bicarbonate 20, BUN 43, creatinine 4.3, blood phosphorus level 12.1 mg/dL (normal 2.5 to 4.8), calcium 5.6 mg/dL (normal 8.5) (Cont.)			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
No Pat Profiles Rptd Unknown			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN-			
#2 CARISOPRODOL (CARISOPRODOL) (Cont.)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 oral		#1 ??/??/??	
#2 oral		#2 ??/??/??	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 SUICIDE AND SELF-INFLICTED POISONING		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 SUICIDE AND SELF-INFLICTED POISONING		#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 (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) No Concomitant Products Reported			

G. All manufacturers		
1. Contact office - name/address (& mfring site for devices)		2. Phone number
R.W. JOHNSON PHARM. RES. INST. USA DIV. OF ORTHO PHARMACEUTICAL CORP. 920 U.S. Route 202 P.O. Box 300 Raritan NJ 08869 USA (Informing Unit)		908-704-4504
4. Date received by manufacturer (mo/day/yr) 07/08/99		3. Report source (check all that apply)
6. If IND, protocol #		<input type="checkbox"/> foreign <input type="checkbox"/> study <input checked="" 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:
7. Type of report (check all that apply)		5. (A) NDA # 85-055
<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		IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes
9. Mfr. report number PRIUSA1999002540		8. Adverse event term(s)
		1) SUICIDE ATTEMPT 2) THERAPEUTIC RESPONSE INCREASED 3) COMA 4) HYPOTENSION 5) ACIDOSIS 6) CYANOSIS (Cont.)

E. Initial reporter			
1. Name, address & phone #			
Dr. Toby Litovitz American Association of Poison Control Centers 3201 New Mexico Ave, Suite 310 Washington, DC 20016 USA Phone #: 202-362-7493			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

RECEIVED DSS
 JUL 22 1999
 JUL 23 1999
 BY: _____

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



3309028-6-00-02

HARM. RES. INST. USA
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999002540
UP/Dist report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 3

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. <input 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 type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> other: _____		
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)		
5. Describe event or problem			
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) #3 NAPROXEN (NAPROXEN) #4 _____ (Cont.)			
2. Dose, frequency & route used #3 oral #4 _____		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #3 ??/??/?/? #4 _____	
4. Diagnosis for use (indication) #3 SUICIDE AND SELF-INFLICTED POISONING #4 _____		5. Event abated after use stopped or dose reduced #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known) #3 _____ #4 _____	7. Exp. date (if known) #3 _____ #4 _____		8. Event reappeared after reintroduction #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # - for product problems only (if known) #4 _____			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office - name/address (& mfring site for devices)		2. Phone number	
4. Date received by manufacturer (mo/day/yr)		5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
6. If IND, protocol #		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input 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: _____	
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		8. Adverse event term(s)	
9. Mfr. report number			
E. Initial reporter			
1. Name, address & phone #			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation BY: _____	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input 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.

Individual Safety Report



3309028-6-00-03

P.O. Box 300
Raritan NJ 08869
USA

Continuation Sheet for FDA-3500A Form

Page 3 of 3

Mfr. report #: PRIUSA1999002540

Date of this report : 07/19/99

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

following electrolytes: sodium 129, potassium 6.4, chloride 90, and bicarbonate 20. BUN was 43 and creatinine was 4.3. The patient had a blood phosphorus level of 12.1 mg/dL (normal 2.5 to 4.8) and calcium of 5.6 mg/dL (normal 8.5 to 10.5). SGOT was 1576 IU/L and SGPT was 416 IU/L. Salicylate level was 2.5 mg/dL and acetaminophen was 6 mcg/mL. White count was 24,000 with 62% poly, 28% bands, and 4% metamyelocytes. A blood myoglobin level was 39,200 (normal 0-76), creatine phosphokinase was 71,420 IU/L (normal 24-170). Clinically the patient became progressively hypotensive and was treated with intravenous fluids. She developed a metabolic acidosis and became progressively cyanotic. The patient was thought to be fluid overloaded in the context of renal insufficiency, and underwent hemodialysis. Following hemodialysis, the patient's respiratory status improved and her mental status was observed to be awake, groggy and communicative. Later on that day she was described as alert, oriented, and appropriate, but not putting out any substantive amount of urine. She confirmed that she had taken an overdose of the above medications. On day 3 of hospitalization, the patient had just returned from dialysis when she developed ventricular tachycardia followed by cardiac arrest. She was resuscitated, but never regained a normal mental status. An aspiration occurred during the resuscitative effort. At the time of endotracheal intubation, the patient was noted to have coffee ground material in the mouth. Following the resuscitative effort, the patient developed anoxic brain injury and adult respiratory distress syndrome. The patient was given aggressive and supportive care but did not improve. On day 9 the family requested the patient be made a "do not resuscitated". The patient had a cardiac arrest and was not resuscitated.

B.6 Relevant tests/laboratory data, including dates (Cont...)

to 10.5), SGOT 1576 IU/L, SGPT 416 IU/L, salicylate level 2.5 mg/dL, white count 24,000 with 62% poly, 28% bands and 4% metamyelocytes, blood myoglobin level 39,200 (normal 0-76), creatine phosphokinase 71,420 IU/L (normal 24-170)

C. Suspect medication (Cont...)

- Seq No. : 1
- C.1 Suspect medication : TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN/CODEINE)
- C.4 Diagnosis for use(indication) : 1) SUICIDE AND SELF-INFLICTED POISONING BY OTHER SPECIFIED DRUGS AND MEDICINAL SUBSTANCES

- Seq No. : 2
- C.1 Suspect medication : CARISOPRODOL (CARISOPRODOL)
- C.4 Diagnosis for use(indication) : 1) SUICIDE AND SELF-INFLICTED POISONING BY OTHER SPECIFIED DRUGS AND MEDICINAL SUBSTANCES

- Seq No. : 3
- C.1 Suspect medication : NAPROXEN (NAPROXEN)
- C.4 Diagnosis for use(indication) : 1) SUICIDE AND SELF-INFLICTED POISONING BY OTHER SPECIFIED DRUGS AND MEDICINAL SUBSTANCES

G. All manufacturers

8. Adverse event term(s)

- 7) RENAL FAILURE ACUTE
- 8) TACHYCARDIA VENTRICULAR
- 9) CARDIAC ARREST
- 10) ASPIRATION
- 11) DYSPNOEA

Source of report (Literature):

- Seq No. : 1
- Author : Toby Litovitz
- Year : 99
- Article title : 1998 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System

DSS
JUL 23 1999

RECEIVED
JUL 22 1999
BY: _____



FDA Use Only

Tringa unit
sequence #

108/bb2

CDER

A. Patient information

1. Patient Identifier: [REDACTED] 2. Age at time of event: 75 or Date of birth: [REDACTED] 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 (mm/dd/yyyy) life-threatening hospitalization - initial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other: _____

3. Date of event: 07/07/99 (mm/dd/yyyy) 4. Date of this report: 8/18/99 (mm/dd/yyyy)

5. Describe event or problem (up to a total of 6400 characters allowed):
Present to ER with recent nausea, vomiting, and hematemesis, weak and dizzy. Has had black tarry stools over 4 weeks. No acute abdominal pain. Admitted for work-up of GI bleed. Blood transfusion given.

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed):
BP 116/50 at admission
Hgb 3.9, platelets 400,000, HCT 13.3;
endoscopy: pyloric channel ulcer, cameron lesions, hiatal hernia.

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed):
Osteoarthritis, osteoporosis, history of peptic ulcer disease

DSS
SEP - 1 1999

CTU 108/bb2

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
#1 Naprosyn / UNK /
#2 Celebrex / 200 /

2. Dose/Frequency/Route used
#1 UNK / /
#2 200 / qd / Oral

3. Therapy dates (if unknown, give duration)
#1 Unk - -
#2 - -

4. Diagnosis for use (separate indications with commas)
#1 osteoarthritis
#2 osteoarthritis

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)
- -

10. Concomitant medical products and therapy dates (up to a total of 1000 characters):
Fosamax 10 mg QD, Ultram 50 mg tid, unknown dates.

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. REC'D.
model #
catalog # SEP 0 1 1999
serial #
lot # MEDWATCH CTU
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)

E. Reporter (see confidentiality section on back)

1. Name [REDACTED] phone # [REDACTED]
Address [REDACTED] 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.



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

MEDWATCH

Approved by FDA on 10/20/93

INDIVIDUAL SAFETY REPORT



3339600-9-00-01

CDER

Page 1 of 3

Triage unit sequence #

108791

A. Patient Information

1. Patient Identifier [redacted] 2. DOB: [redacted] 13. Sex: [redacted] 14. Weight: [redacted]
AGE: 85 yrs MALE 110.2 kg

C. Suspect Medication(s)

11. Name #1: NAPROSYN

#2: PREDNISONE 20MG TAB

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem

2. Outcomes attributed to adverse event

- [] death; [] life-threatening; [X] Hospitalization initial or prolonged; [] disability; [] congenital anomaly; [X] required intervention to prevent impairment/damage; [] other

12. Dose, frequency & route used 13. Therapy dates

#1: #2:

14. Diagnosis For use (indication) 15. Event abated after use stopped or dose reduced? #1: [N/A] #2: [N/A]

3. Date of event 06/26/99 14. Date of this report 08/02/99

5. Describe event or problem GASTROINTESTINAL BLEED, SYNCOPE

16. Lot # (if known) 17. Exp. date 18. Event reappeared after reintroduction #1: #2: #1: [] #2: []

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

19. (Not applicable to adverse reports) 10. Concomitant medical products (therapy dates) (exclude treatment) 9/2/1999

MEDWATCH CTU

7. Other relevant history, including pre-existing medical conditions

86 Y/O MALE W/ H/O COPD, CHF, CRI, OSTEOARTHRITIS, TIMEA PEDIS, HEARING IMPAIRMENT IS ADMITTED TO DALLAS VA MEDICAL CENTER WITH SYNCOPE, SOB, CHEST PAIN. PT HAS HAD POSITIVE STOOL. PT HAD DIARRHEA X3 DAYS PTA. PT RECENTLY PLEASE SEE ATTACHED

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

11. Name, address & phone # [redacted] ROAD

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

or FAX to: 1-800-FDA-0178

12. Health professional? 13. Occupation 14. Reported to Mfr. [YES] PHARMACIST [NO]

15. 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.

DSS

SEP 17 1999

RECEIVED MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

ADVERSE EVENT REPORTING SYSTEM

HF-2

CTU 108791

SUSPECT MEDICATION: NAPROSYN

DATE OF EVENT: 6/26/99

108791

Relevant Test/Laboratory Data Continued:

- TEST: HEMOGLOBIN RESULTS: H 146 mmol/L H:145/L:133 COLLECTION DATE: 6/28/9904:37
- TEST: HEMATOCRIT RESULTS: H 110.0 mmol/L H:108/L:96 COLLECTION DATE: 6/28/9904:37
- TEST: UREA NITROGEN RESULTS: H 60 mg/dL H:20/L:6 COLLECTION DATE: 6/28/9904:37
- TEST: CREATININE RESULTS: 1.2 mg/dL H:1.2/L:.5 COLLECTION DATE: 6/28/9904:37
- TEST: RBC RESULTS: L 3.52 K/cu mm H:5.8/L:4.3 COLLECTION DATE: 6/28/9904:37
- TEST: HGB RESULTS: L 11.0 g/dL H:17.3/L:13 COLLECTION DATE: 6/28/9904:37
- TEST: HCT RESULTS: L 33.0 % H:52/L:38 COLLECTION DATE: 6/28/9904:37
- TEST: MEUT Z RESULTS: H 89.6 % H:80/L:37 COLLECTION DATE: 6/28/9904:37
- TEST: UREA NITROGEN RESULTS: H 75 mg/dL H:20/L:6 COLLECTION DATE: 6/27/9904:37
- TEST: CREATININE RESULTS: H 1.6 mg/dL H:1.2/L:.5 COLLECTION DATE: 6/27/9904:37
- TEST: DSNO/CA RESULTS: H 307 mosn/kg H:295/L:265 COLLECTION DATE: 6/27/9904:37
- TEST: HBC RESULTS: H 17.2 K/cu mm H:11/L:4 COLLECTION DATE: 6/27/9904:37
- TEST: RBC RESULTS: L 3.05 K/cu mm H:5.8/L:4.3 COLLECTION DATE: 6/27/9904:37
- TEST: HGB RESULTS: L 9.6 g/dL H:17.3/L:13 COLLECTION DATE: 6/27/9904:37
- TEST: HCT RESULTS: L 28.8 % H:52/L:38 COLLECTION DATE: 6/27/9904:37
- TEST: HGB RESULTS: L 9.4 g/dL H:17.3/L:13 COLLECTION DATE: 6/27/9904:37
- TEST: HCT RESULTS: L 28.2 % H:52/L:38 COLLECTION DATE: 6/27/9904:37
- TEST: PLATELETS RESULTS: 202.0 K/cu mm H:400/L:140 COLLECTION DATE: 6/27/9904:37
- TEST: TROPONIN-I RESULTS: <0.5 ng/mL COLLECTION DATE: 6/27/9904:37
- TEST: CPK RESULTS: 59 U/L H:195/L:24 COLLECTION DATE: 6/27/9904:37
- TEST: UREA NITROGEN RESULTS: H 116 mg/dL H:20/L:6 COLLECTION DATE: 6/27/9904:31
- TEST: CREATININE RESULTS: H 2.3 mg/dL H:1.2/L:.5 COLLECTION DATE: 6/27/9904:31
- TEST: CALCIUM RESULTS: L 7.7 mg/dL H:10.2/L:8.4 COLLECTION DATE: 6/27/9904:31
- TEST: P04 RESULTS: H 5.7 mg/dL H:4.5/L:2.4 COLLECTION DATE: 6/27/9904:31
- TEST: DSNO/CA RESULTS: H 314 mosn/kg H:295/L:265 COLLECTION DATE: 6/27/9904:31
- TEST: INR RESULTS: 0.98 COLLECTION DATE: 6/27/9904:31
- TEST: PTT RESULTS: L 18.8 Sec. H:35.6/L:24 COLLECTION DATE: 6/27/9904:31
- TEST: HGB RESULTS: L 9.8 g/dL H:17.3/L:13 COLLECTION DATE: 6/27/9904:31
- TEST: HCT RESULTS: L 29.0 % H:52/L:38 COLLECTION DATE: 6/27/9904:31
- TEST: PLATELETS RESULTS: 217.0 K/cu mm H:400/L:140 COLLECTION DATE: 6/26/99023:29
- TEST: PLATELET-ESTH RESULTS: Adeq. COLLECTION DATE: 6/26/99023:29
- TEST: UREA NITROGEN RESULTS: H 123 mg/dL H:20/L:6 COLLECTION DATE: 6/26/99021:42
- TEST: CREATININE RESULTS: H 2.6 mg/dL H:1.2/L:.5 COLLECTION DATE: 6/26/99021:42
- TEST: DSNO/CA RESULTS: H 307 mosn/kg H:295/L:265 COLLECTION DATE: 6/26/99021:42
- TEST: THEOPHYLLINE RESULTS: 14.4 ug/mL H:20/L:10 COLLECTION DATE: 6/26/99017:21
- TEST: HGB RESULTS: L 7.8 g/dL H:17.3/L:13 COLLECTION DATE: 6/26/99017:21
- TEST: HCT RESULTS: L 23.9 % H:52/L:38 COLLECTION DATE: 6/26/99017:21
- TEST: PLATELETS RESULTS: 271.0 K/cu mm H:400/L:140 COLLECTION DATE: 6/26/99017:21
- TEST: TRIGLYCERIDE RESULTS: 166 mg/dL H:200/L:0 COLLECTION DATE: 6/26/99010:31
- TEST: CHOLESTEROL RESULTS: 111 mg/dL H:200/L:0 COLLECTION DATE: 6/26/99010:31
- TEST: T PROT RESULTS: L 5.1 G/dL H:0.4/L:5.9 COLLECTION DATE: 6/26/99010:31
- TEST: ALBUMIN RESULTS: L 3.0 G/dL H:5.2/L:3.2 COLLECTION DATE: 6/26/99010:31
- TEST: P04 RESULTS: H 6.1 mg/dL H:4.5/L:2.4 COLLECTION DATE: 6/26/99010:31
- TEST: DSNO/CA RESULTS: H 301 mosn/kg H:295/L:265 COLLECTION DATE: 6/26/99010:31
- TEST: PROTHROMBIN TIME RESULTS: 11.6 Sec. H:13.1/L:10.7 COLLECTION DATE: 6/26/99010:31
- TEST: INR RESULTS: 0.95 COLLECTION DATE: 6/26/99010:31
- TEST: PTT RESULTS: L 17.5 Sec. H:35.6/L:24 COLLECTION DATE: 6/26/99010:31
- TEST: HBC RESULTS: H 26.7 K/cu mm H:11/L:4 COLLECTION DATE: 6/26/99010:31
- TEST: RBC RESULTS: L 2.43 K/cu mm H:5.8/L:4.3 COLLECTION DATE: 6/26/99010:31
- TEST: HGB RESULTS: L 7.8 g/dL H:17.3/L:13 COLLECTION DATE: 6/26/99010:31
- TEST: HCT RESULTS: L 23.3 % H:52/L:38 COLLECTION DATE: 6/26/99010:31

DSS

SEP 02 1999

ADVERSE EVENT REPORTING SYSTEM

Individual Safety Report



3339600-9-00-02

CTU 108791

Individual Safety Report



OPTIONAL reporting
professionals of adverse
and product problems

Form Approved: OMB No. 0910-0291 Expires: 4/30/98
See OMB statement on reverse

FDA Use Only
Triage unit sequence # **109196**

CDER
CDER

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier XX In confidence	2. Age at time of event: 63 Years 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 (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) 06/18/1999

4. Date of this report (mm/dd/yyyy) 09/08/1999

5. Describe event or problem (up to a total of 6400 characters allowed)

GASTROINTESTINAL BLEEDING D/T
IBUPROFEN/NAPROXEN. Patient was taking Ibuprofen/Naproxen x 6 months; developed melena + Hematemesis; treated at OH x 4 days; endoscopy showed Duodenal Ulcer; Discharged from OH with RX for Prilosec but he couldnt afford it. Developed tarry stools + dark brown emesis and came to this hospital. At this hospital, his GI bleeding cleared with 14L gastric lavage. Given IV Fluids and 2 units PRBCs. Discharged 5 days after admission.

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 09 1999

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	2. Dose/Frequency/Route used		3. Therapy dates (if unknown, give duration)	
#1 IBUPROFEN / /	#1 / /	#1 From - To (or best estimate)		
#2 NAPROXEN / /	#2 / /	#2 - -		
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced			
#1	#1 <input 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 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 (up to a total of 1000 characters)				

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 # _____
catalog # **SEP 09 1999**
serial # _____
lot # **MEDWATCH CTU**
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)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____

Address _____ E-mail (for electronic acknowledgement) _____

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 20852-8787



FDA Form 3500 (WWW)

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

CTU 109196



CDER
or VOLUNTARY reporting by health professionals of adverse events and product problems
Triage Unit Sequence # 109407

The FDA Medical Products Reporting Program

Page 1 of 1
CDER

SYSTEM ELECTRONIC 3500 FORM ADAPTATION, Version 1.01, September 1997

A. Patient Information

1. Patient Identifier: [REDACTED] 2028
2. Age at time of event: [REDACTED] or Date of birth: [REDACTED]
3. Sex: F 4. Weight: 90 kgs

B. Adverse Event or Product Problem

1. Adverse Event and/or Product Problem

2. Outcomes attributed to adverse event:
 Death Disability
 Life-threatening Congenital anomaly
 Hospitalization - initial Required intervention to prevent permanent impairment/damage
 Hospitalization - prolonged

3. Date of event (mo/day/yr): 4/5/99 4. Date of this report (mo/day/yr): 9/10/99

5. Describe event or problem:
 A pharmacist reported that a patient began taking unspecified regimens of ibuprofen, naproxen, Goody's powders, and Excedrin approximately two weeks ago for knee pain. On 5-Apr-99 the patient presented to the emergency care center with GASTROINTESTINAL ULCERATION, GASTROINTESTINAL BLEEDING, and HEMATEMESIS. The patient was ADMITTED TO THE HOSPITAL, where the suspected drugs were discontinued. Treatment was initiated with famotidine 20 mg intravenously every 12 hours. The reaction was reported to have resolved.

6. Relevant tests/laboratory data, including dates:
 Serum Creatinine: 0.6
 None noted

7. Other relevant history, including preexisting medical conditions:
 Allergies: NKDA
 None noted

C. Suspect Medication(s)

1. Name (give labeled strength mfr/labeler, if known):
 #1 naproxen sodium (Naprosyn)
 #2 aspirin/acetaminophen/caffeine (Goody's)

2. Dose, frequency, route used: #1 unk #2 unknown
 3. Therapy Dates (from/to): #1 2 weeks #2 2 weeks

4. Diagnosis for use (indication): #1 #2
 5. Event abated after use stopped or dose reduced: #1 Yes #2

6. Lot # (if known): #1 #2 7. Exp. date: #1 #2
 8. Event reappeared after reintroduction: #1 Unknown #2

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

10. Concomitant medical products:
 acetaminophen
 acetaminophen/codeine
REC'D.
SEP 13 1999

D. Suspect Medication
MEDWATCH CTU
 These fields not used for electronic 3500 reporting at [REDACTED]

Internal ADR Event Coding

Reaction 1:	hematemesis
Reaction 2:	gastrointestinal ulceration
Reaction 3:	gastrointestinal bleeding
Reaction 4:	
Reaction 5:	

E. Reporter (see confidentiality section on back)

1. Name, address and phone #:
 ADR Program Coordinator / Drug Information Service
 Department of Pharmacy and Drug Information
 [REDACTED] Box [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.

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville MD 20852 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

CT4109407

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

HF-2

DSS
SEP 13 1999
** TOTAL PAGE: 024 **

Individual Safety Report



3346069-7-00-01



Page 1 of 2

Approved by FDA on 12/02/93

Mfr report #	9932334
UF/Dist report #	
FDA Use Only	

*+ indicates item continued

A. Patient Information

1. Patient Identifier [REDACTED]	2. Age at time of event: 46 YRS or Date of Birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 180.0 lbs or [REDACTED] kgs
-------------------------------------	--	---	--

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 from/to (or best estimates))
# 1 ZOLOFT TABLETS	# 1 UNKNOWN	# 1 11/-/98 - UNKNOWN
# 2 NAPROSYN	# 2 UNKNOWN	# 2 11/-/98 - UNKNOWN
4. Diagnosis for use (indications)	5. Event abated after use stopped or dose reduced	
# 1 HEAD INJURY PAIN	# 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
# 2 HEAD INJURY PAIN	# 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)	8. Event reappeared after reintroduction
# 1 UNKNOWN	# 1 UNKNOWN	# 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
# 2 UNKNOWN	# 2 UNKNOWN	# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" 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)		
ESTROGEN REPLACEMENT THERAPY UNKNOWN - 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) disability

life-threatening congenital anomaly

hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage

other: _____

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

4. Date of this report 09/10/99 (mo/day/yr)

5. Describe event or problem

THIS IS A SECOND FOLLOW-UP REPORT BASED ON INFORMATION RECEIVED BY PFIZER ON 26AUG99. THE FIRST FOLLOW-UP REPORT WAS SUBMITTED ON 25AUG99. THE INITIAL REPORT WAS SUBMITTED ON 29JUL99.

THIS 46-YEAR-OLD FEMALE CONSUMER WAS STARTED ON ZOLOFT (SERTRALINE) AND NAPROSYN (NAPROXEN) FOR HEAD INJURY PAIN IN NOV98. RIGHT AFTER STARTING ZOLOFT SHE EXPERIENCED LOOSE STOOL WHICH SUBSIDED WITH CONTINUED USE OF ZOLOFT. IN DEC98 SHE BEGAN TO EXPERIENCE STOMACH PAIN. SHE STARTED TAKING NAPROSYN LESS FREQUENTLY BUT CONTINUED ZOLOFT. AFTER SEVERAL WEEKS SHE DISCONTINUED NAPROSYN AND STOPPED ZOLOFT DUE TO THE STOMACH PAIN. SHE ALSO REPORTS HER STOOLS ARE YELLOW AND THAT SHE WAS IN BED EVERYDAY. ON 31DEC98 SHE HAD A COMPUTERIZED AXIAL TOMOGRAPHY OF HER ABDOMEN AND LUNGS. AT SOME UNKNOWN POINT AFTER STARTING ZOLOFT SHE HAD A SKIN REACTION WHICH CONSISTED OF HER EARS AND FACE TURNING RED AFTER SHE ATE. ON 31DEC98 BLOOD TESTS REVEALED ELEVATED "GALLBLADDER ENZYMES" POSSIBLY DUE TO A BLOCKED BILE DUCT. IN JAN99 HER STOMACH FELT WORSE AND SHE WENT TO THE EMERGENCY ROOM. IN JAN99 HER LIVER ENZYMES WERE ELEVATED AND ENDOSCOPY SHOWED SHE HAD A PEPTIC ULCER WITH NO BACTERIAL INVOLVEMENT. SHE WAS STARTED

6. Relevant tests/laboratory data, including dates

31DEC98: COMPUTERIZED AXIAL TOMOGRAPHY OF THE ABDOMEN AND LUNGS; BLOOD WORK REVEALED ELEVATED "GALLBLADDER ENZYMES".

JAN99: ELEVATED LIVER ENZYMES

JAN99: ENDOSCOPY, PEPTIC ULCER WITH NO BACTERIAL INVOLVEMENT.

FEB99: TWO ENDOSCOPIES-SHOW ULCER

APR99: ENDOSCOPY-ULCER STARTED TO HEAL.

01JAN99- ABDOMINAL COMPUTERIZED TOMOGRAPHY SHOWED A NORMAL LIVER

19APR99- NORMAL LIVER FUNCTION TESTS

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

OTHER

-GALLBLADDER REMOVED

OTHER

-USE OF ASPIRIN

DSS

SEP 14 1999

G. All manufacturers

1. Contact office - name/address (& mfring 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)	3. Report source (check all that apply)
08/26/99	<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:
5. (A) NDA # NDA #19-839 IND # PLA #	8. Adverse event term(s)
pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	PEPTIC ULCER HEPATITIS DIARRHEA DIARRHEA LIVER FUNCTION TESTS ABNORMAL BASE ABNORMAL STOOLS GALL BLADDER/BILIARY TRACT DISORDER
6. If IND, protocol #	9. Mfr. report number
N/A	9932334
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 type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 2	

E. Initial reporter

1. Name, address & phone #

[REDACTED] ST. STE. [REDACTED]

US

Tel. [REDACTED]

SEP 13 1999



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

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation RETAIL SALES	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
--	-------------------------------	---



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9932334

B5. EVENT DESCRIPTION - Continued

ON PRILOSEC (OMEPRAZOLE) TO TREAT THE ULCER. IN FEB99 SHE HAD TWO ENDOSCOPIES WHICH SHOWED SHE STILL HAD THE ULCER. IN APR99 AN ENDOSCOPY SHOWED THAT THE ULCER STARTED TO HEAL. IN '99 SHE TOOK "MILK THISTLE FOR THE ULCER." ON 12JUL99 SHE RESTARTED ZOLOFT, "THE BLUE TABLET" AND SUBSEQUENTLY ON 13JUL99 SHE EXPERIENCED LOOSE STOOLS. ZOLOFT HELPS THE HEAD INJURY PAIN. ON 16JUL99 SHE HAD BACK PAIN WHICH IS A MANIFESTATION OF HER ULCER PAIN AND BEGAN "FEELING BAD." ADDITIONAL INFORMATION RECEIVED FROM THE GASTROENTEROLOGIST STATES THAT THE PATIENT ALSO EXPERIENCED DIARRHEA AND HEPATITIS. IT IS NOT CLEAR THAT HER SYMPTOMS ARE ATTRIBUTABLE TO SERTRALINE AND/OR NAPROSYN (NAPROXEN). ON 01JAN99, COMPUTERIZED TOMOGRAPHY SHOWED A NORMAL LIVER. ON 19APR99 HER LIVER FUNCTION TESTS WERE NORMAL. ON 14MAY99, A MAGNETIC RESONANCE IMAGE WAS NORMAL. ADDITIONAL INFORMATION FROM A PHYSICIAN STATES THAT HE PRESCRIBED ZOLOFT (SERTRALINE) FOR HER SINCE ABOUT THREE MONTHS PRIOR TO 09AUG99, WHEN HE LAST SAW HER. SHE REPORTED "GASTRIC UPSET". SHE DID NOT MENTION YELLOW STOOL, SUSPECTED OBSTRUCTED BILE DUCT, ERYTHEMATOUS SKIN RASH, ELEVATED LIVER ENZYMES, PEPTIC ULCER. ACCORDING TO HIS RECORDS, THE ONLY OTHER MEDICATION SHE WAS TAKING WAS ESTROGEN REPLACEMENT THERAPY, WHICH WAS BEING MANAGED BY ANOTHER PHYSICIAN.

B6. RELEVANT TESTS/LAB. DATA - Continued

14MAY99- NORMAL MAGNETIC RESONANCE IMAGE

E1. NAME AND ADDRESS OF REPORTER - Continued

[REDACTED] MD
[REDACTED] AVENUE

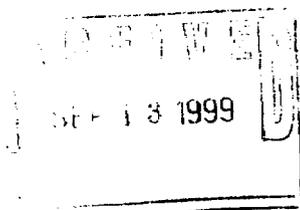
US
Tel. - [REDACTED]

DR. [REDACTED]
[REDACTED] FAMILY PRACTICE, INC.
[REDACTED] AVENUE

Tel. [REDACTED]

DSS

SEP 14 1999





3356987-1-00-01

CDER

CDER

110322

Adverse Drug Events Data Collection Form

2/99

Patient Demographics

Patients Name: [redacted] #3080
Patients SSN: [redacted] Location: [redacted] Age: 46 Sex: Male Female

Cause

Suspected Drug(s): naproxen Dose/Route/Frequency: [redacted]
Indication: pain Date of Reaction: 2/3/99 Time: [redacted]

ADE Description

Occurred before admission to hospital? YES NO
Describe event or problem: Name of Prescriber notified: [redacted]

pt. was admitted to ICU for bleeding w/ gastric & duodenal ulcers 2° to NSAIDs

Name of Person completing report: [redacted] PharmD Date: 2/99

Was report forwarded to FDA? YES NO

Intervention Approach

Steroid Antihistamine Ephinephrine Antidote Drug D/Ced Other: [redacted]

Outcome of Reaction: hospitalized - recovered

Was this an Adverse Drug Event?

- Doubtful
- Possible
- Probable

Mechanism:

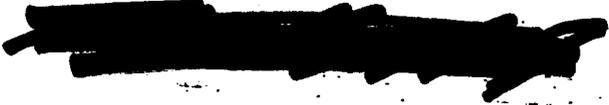
- Allergic
- Idiosyncratic
- Irritant
- Pharmacologic

Other relevant history, including preexisting medical conditions:

HTN, brachial neuropathy

Relevant tests or lab data including dates:

B'ham VAMC
700 19th St.
B'ham, AL 35233



REC'D.

SEP 27 1999

MEDWATCH CTU

DSS

SEP 27 1999

ADVERSE EVENT REPORTING SYSTEM

RECEIVED
MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM
HF-2

CTU110322

SEP.



3357287-6-00-01

CDER

CDER

Adverse Drug Events Data Collection Form

Patient Demographics

Patient's Name: [redacted] Patients SSN: [redacted] Location: [redacted] Age: 49 Sex: Male X Female

Cause

Suspected Drug(s): Naproxen / Heparin Dose/Route/Frequency: [redacted] Indication: [redacted] Date of Reaction: 4/17/99 Time: [redacted]

ADE Description

Occurred before admission to hospital? YES X NO [] Describe event or problem: Hematemesis, gastritis, duodenitis, and Mallory-Weiss tear Name of Prescriber notified: [redacted]

Name of Person completing report: [redacted] Date: 4/99 Was report forwarded to FDA? YES [] NO []

Intervention Approach

Steroid [] Antihistamine [] Ephinephrine [] Antidote [] Drug D/Ced [] Other: []

Outcome of Reaction: Hospitalized, Recovered.

Was this an Adverse Drug Event?

- Doubtful [] Possible X Probable []

Mechanisms:

- Allergic [] Idiosyncratic [] Irritant [] Pharmacologic X

Other relevant history, including preexisting medical conditions:

DVT, Alcohol abuse, Pulmonary Tuberculosis

Relevant tests or lab data including dates:

B'ham VAMC 700 19th St. B'ham, AL 35233

REC'D.

SEP 24 1999

MEDWATCH CTU

RECEIVED MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

DSS

SEP 27 1999

ADVERSE EVENT REPORTING SYSTEM

CTU 110294

MF-2

Individual Safety Report



3364970-5-00-01

CDEP

Voluntary reporting
by health professionals of adverse
events and product problems

Form Approved OMB No. 0919-0281 Expires 4/98
See OMB Statement on PVS

FDA Use Only

Triangle unit
response # 110859

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier XX In confidence	2. Age at time of event: 60 y 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) **6-25-99**

4. Date of this report (mm/dd/yyyy) **10-5-99**

5. Describe event or problem (up to a total of 6400 characters allowed)

Gastrointestinal Bleed: Melena. Pt takes Aspirin 325mg QD & Naproxen 1 BID on + off for H/A, admitted b/o d/o epigastric Pain & melena x 5 days. EGD showed multiple clear basal ulcers in body & antrum of stomach + single duodenal ulcer. BX showed H. pylori. NSAID's Dcd, begun on H. pylori regimen.

**Improved + Discharged
3 Days p Admission.**

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

OCT 7 1999

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 naproxen / /	#1 / /	#1 From - To (for best estimate)
#2 ASPIRIN / /	#2 / /	#2 -
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced	
#1	#1 <input 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 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 (up to a total of 1000 characters)		

D. Suspect medical device

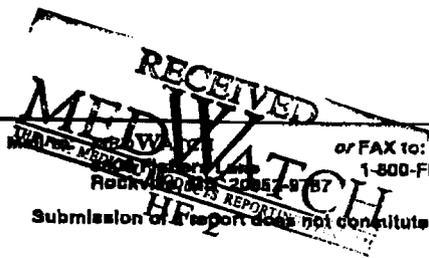
1. Brand name	4. Operator of device
2. Type of device	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
3. Manufacturer name & address	5. Expiration date (mm/dd/yyyy)
6. Model #	7. If implanted, give date (mm/dd/yyyy)
catalog # REG'D.	8. If explanted, give date (mm/dd/yyyy)
serial #	
lot # MEDWATCH CTU	
other #	
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 (up to a total of 1000 characters)	

E. Reporter (see confidentiality section on back)

1. Name	phone #
Address	
Med Center	
St. RM	
E-mail (for electronic acknowledgment)	
2. Health professional?	3. Occupation
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacist
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"/>	



FDA Form 3500 (WWW)



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.

110859 OCT 6 '99 AM 7:02

INDIVIDUAL Safety Report



5/99-37

MEDWatch

CVÉR

Approved by FDA on 10/20/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 111070

Page 1 of 1

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight | AGE: 49 yrs | MALE | 84.8 kg

C. Suspect Medication(s)

1. Name | #1 : NAPROXEN SODIUM (ALEVE)

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem

2. Outcomes attributed to adverse event

- [] death, [] life-threatening, [X] Hospitalization, [] disability, [] congenital anomaly, [] required intervention to prevent impairment/damage, [] other

2. Dose, frequency & route used | 3. Therapy dates | #1: PRNORAL | #1 : -04/27/99

4. Diagnosis for use (indication) | 5. Event abated after use | #1: DJD/GOUT | #1: [N/A]

3. Date of event | 4. Date of this report | 04/27/99 | 09/09/99

5. Describe event or problem | ABDOMINAL PAIN , GI BLEED

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

9. (Not applicable to adverse drug event reports)

6. Relevant test/laboratory data. including dates

REC'D.

OCT 08 1999

MEDWATCH CTU

10. Concomitant medical products/therapy dates (exclude treatment) | LANSOPRAZOLE CAP, SA 04/27/99-04/30/99 | PHYTONADIONE INJ 04/27/99-04/29/99

7. Other relevant History, including preexisting medical conditions

NOTE DATED: 04/28/99 11:01 MEDICINE ATTENDING ADMITTED: 04/27/99 14:14 7-S MED 49 yo bm, retired hospital worker, with a long history of djd and gout presents with abd pain and dark red stool x 4 days. He has eschewed allopurinol PLEASE SEE ATTACHED

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] | 915 N. GRAND [REDACTED] | ST. LOUIS, MISSOURI 63106 [REDACTED]

2. Health professional? | 3. Occupation | 4. Reported to Mfr. | [] | [PROGRAM ANALYS] | [NO]

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

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

or FAX to: | 1-800-FDA-0178

Form 3500

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

CTU 111070

OCT 8 1999



5/99-111070
0111

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: NAPROXEN

DATE OF EVENT: 4/27/99

S. B. Part 7. Other Relevant History Continued

and other gout prophylaxis and prefers to take nsaids prn, often in high doses, with occ aspirations of l knee. He had taken a great deal of naproxen prior to this episode. He noted dull midgastric and rug pain during this time.

pe as noted. Today his abd is benign without local tenderness, nl bs. He was slightly orthostatic despite fluid resuscitation.

Agree with dx of probable ugib, ppt by nsaid abuse. He is presently stable and does not appear to need transfusion. He will be evaluated by gi and probably scoped. He needs to take prophylactic antigout meds and may be a candidate for COX-2 inhibitor.

Signed by: [REDACTED]

Staff Physician 04/28/99 11:07

THIS ADVERSE DRUG EVENT HAS BEEN DOCUMENTED THE PATIENT'S INPATIENT AND OUTPATIENT MEDICATION PROFILES.

ADDENDUM: This case was discussed at the June meeting of the P&T QA Committee. Members said that he was apparently taking more than the recommended dose (500 mg BID) of naproxen for DJD. Naproxen was discontinued and he was advised not to take any NSAIDs, including OTC NSAIDs in the future. His pain was to be treated with acetaminophen instead. They believed case was handled appropriately.



OCT 8 1999

CTU 111070

5/99 - 11070

Jun 15, 1999 11:34 ST LOUIS, MO (CONS)

INDIVIDUAL Safety REPORT

List for [REDACTED]



copy- DO NOT PUT IN PATIENT'S CHART

3367079-X-00-03

4041 [REDACTED]

	Na	K	CL	CO2	GLU	BUN	CREAT
04/29/1999 06:00	139	4.2	109H	28	128H	11	1.2
04/28/1999 06:00	138	4.7	110H	25	140H	18	1.1
04/27/1999 18:02	141	4.7	109H	24	129H	21H	1.0

	WBC	HGB	HCT	PLT	MCV	RBC	MCH
04/30/1999 06:00	9.82	10.6L	33.1L	280	91.2	3.63L	29.1
04/29/1999 24:00	10.8	10.2L	32.2L	245	90.5	3.56L	28.6
04/29/1999 06:00	8.22	9.67L	31.1L	232	92.1	3.38L	28.6
04/28/1999 21:00	10.1	10.3L	32.8L	256	90.8	3.61L	28.4
04/28/1999 13:56	8.39	9.95L	31.2L	235	91.8	3.4L	29.3
04/28/1999 06:00	9.06	11.2L	35.6L	277	91.2	3.9L	28.7
04/27/1999 23:00	12.1H	11.3L	35L	289	90.3	3.87L	29.1
04/27/1999 18:02	12.1H	12.2L	38L	280	89.5	4.25L	28.7

	GOT	GPT	AKP	LDH	TBIL	D.BILI	GMMAGT
04/28/1999 06:00	20		43		0.9		

	T.Prot	ALB	CHOL	TRIG	CLCIUM	PO4	U.ACID
04/28/1999 06:00	6.4	3.4L			8.8		

	PROTIME	PTT	INR	ZTHROMB	BL.TIME	FIBRINO	FDP
9/1999 06:00	13.2H	20.2L	1.17				
1999 06:00	13.1H	20.3L	1.16				
1999 18:02	14.0H	19.8L	1.24				

CTU 111070

OCT 8 1999

Individual Safety Report



VOLUNTARY reporting CDER
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0201 Expires 10/31/00
See OMB statement on reporter

File this only
112454

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 01 of CDER

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 77
or Date of birth: [redacted]

3. Sex: female male

4. Weight: 145 lbs or kg

B. Adverse event or product problem

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

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: 9-7-99

4. Date of this report: 9-19-99

5. Describe event or problem

pt admitted with perforated duodenum taken secondary to prednisone, naproxen and ASA for rheumatoid arthritis

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.)

CAD, HTN, osteoporosis, rheumatoid arthritis, stroke post cerebral spine fusion

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known):
 #1 Naprosyn PREDNISONE
 #2 Estria ECOTRIN Prednisone 5mg bid

2. Dose, frequency & route used:
 #1 [redacted]
 #2 ad

3. Therapy dates (if unknown give duration):
 #1 [redacted]
 #2 [redacted]

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

5. Event started 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 recurred after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only): [redacted]

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

D. Suspect medical device

1. Brand name: DSS

2. Type of device: [redacted]

3. Manufacturer name & address: NOV 8 - 1999

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

5. Expiration date (month/year):

6. Model #: ADVERSE EVENT REPORTING SYSTEM
 Catalog #: NOV 0 8 1999
 Serial #: MEDWATCH CTU
 Lot #: [redacted]
 Other #: [redacted]

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

8. If implanted, give dose (month/year):

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

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

E. Reporter (use confidentiality section on back)

1. Name, address & phone #:
 [redacted] Pharm.D. Pharmacy Department
 [redacted] Hospitals [redacted] St
 [redacted] Tel [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.

PLEASE TYPE OR USE BLACK INK



Mail to: MEDWATCH, 8800 Fishers Lane, Rockville, MD 20852-0787
FAX to: 1-800-FDA-0178

FDA Form 3023 (2/99)

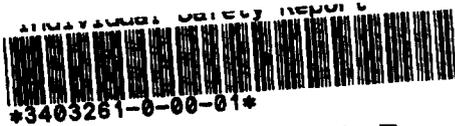
Submission of a report does not constitute an admission that medical error or the product caused or contributed to the event.

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MEDWATCH
MEDICAL PRODUCTS REPORTING PROGRAM

CTU 112454
NOV 8 '99 AM 7:47

HR-2



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Voluntary reporting
by health professionals of adverse
events and product problems
CDER

CDER

Form Approved: OMB No. 0910-0291 Expires: 02-98
See OMB statement on rev.

FDA Use Only	
Trace Unit response #	113176

A. Patient information

1. Patient identifier XX In confidence	2. Age at time of event 63 yr or Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> 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)

<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 (mm/dd/yyyy) **11-4-99**

4. Date of this report (mm/dd/yyyy) **11-19-99**

5. Describe event or problem (up to a total of 6400 characters allowed)

GI Bleed: Hematemesis & Melena. Patient taking ibuprofen & Naproxen for leg pain presents to Emer Room c/o coffee ground emesis (no h/o previous GI Bleed). Guaic positive stool. Treated w/ IVF, NG lavage and admitted. DC'd 4 days after admit.

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

REC'D.

NOV 22 1999

MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

NOV 19 '99 PM 5:12

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MEDWATCH

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 IBUPROFEN /	/
#2 NAPROXEN /	/
2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 / /	#1 From - To (or best estimate) -
#2 / /	#2 -
4. Disposition for use (separate indications with commas)	5. Event abated after use stopped or dose reduced
#1 _____	#1 <input 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. NDC # (for product problems only)	8. Event reappeared after reintroduction
#1 _____	#1 <input 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

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

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 # **NOV 22 1999**

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)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____

Address _____ Med Center _____ St. RM _____

E-mail (for electronic acknowledgment) _____

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
Bethesda, MD 20892-0707

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.

INDIVIDUAL SAFETY REPORT



health professionals of adverse events and product problems

CDEF

FDA Use Only

Triangle unit number 119639

Page of

CDEF

A. Patient Information

1. Patient Identifier 79-43-93 In confidence	2. Age at time of event: 37 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 132 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)

<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/yyyy): 08/17/99

4. Date of this report (m/d/yyyy): 11/29/99

5. Describe event or problem

- Gastric ulcer scan
- upper GI Bleeding
- Anemia

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 (19.4), RBC (2.34), platelet (393).

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

Rib fracture

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 / day prn

3. Therapy dates (if unknown, give duration)

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)

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
ADVERSE EVENT REPORTING
DEC 02 1999

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 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)

E. Reporter (see confidentiality section on back)

1. Name, address & phone

MS, RPL
Medical Center

2. Health professional? yes no

3. Occupation: Pharmacist

4. Also reported to

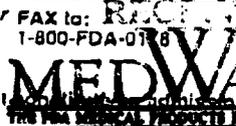
manufacturer
 user facility
 distributor

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: 1-800-FDA-0178



Submission of a report does not constitute an admission of fault by the reporter, personnel or the product caused or contributed to the event.



VOLUNTARY reporting
alt professionals of adverse
nts and product problems

Form Approved: OMB No. 0310-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

113797

Page CDER of CDER

CDER

A. Patient information

1. Patient identifier <u>05-68-05</u> In confidence	2. Age at time of event: <u>86.8</u> or Date of birth: <u>[redacted]</u>	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or <u>59.9</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 checked="" 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) 06/17/99

4. Date of this report (mo/day/yr) 11/17/99

5. Describe event or problem

- Perforated gastric ulcer
- Anemia

DSS
DEC 0 8 1999
ADVERSE EVENT REPORTING SYSTEM

6. Relevant tests/laboratory data, including dates

*Epigastric pain, N/V, Melena,
WBC (4.9), Hgb (6.9), Hct (21.1),
platelet (920), RBC (3.34).*

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

- Autos. s
- Hyper-potassemia
- Ascites
- Septicemia
- Polymyalgia Rheumatica
- Osteoporosis

C. Suspect medication(s)

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

#1 Motrin

#2 Naprosyn

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 Polymyalgia Rheumatica

#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. **REC'D.**
model # _____
catalog # DEC 0 8 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

[redacted] MS, RPh.
Medical 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:
1-800-FDA-0178

FOA 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.



3467227-7-00-01

VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: OMB No. 0918-0291 Expires: 03/31/00 See OMB statement on reverse

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

FDA Use Only

Triage unit sequence # 118094

A. Patient information

1. Patient identifier 1016293 In confidence
2. Age at time of event: 87 Years
3. Sex [X] female [] male
4. Weight ___ lbs or ___ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [] Product problem
2. Outcomes attributed to adverse event
[] death
[] life-threatening
[X] hospitalization - initial or prolonged
[] disability
[] congenital anomaly
[] required intervention to prevent permanent impairment/damage
[] other:
3. Date of event 01/16/2000
4. Date of this report 02/29/2000

5. Describe event or problem
Upper GI bleed: Patient developed hematemesis, esophagitis, anemia and was found to have an upper GI bleed

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions
Pt had been taking ASA 325 mg PO qd for years with no history of gastric ulcers

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
#1 Naprosyn / unknown / unknown
#2 Aspirin / 325 mg / unknown
2. Dose/Frequency/Route used
#1 unkn / unknow / Oral
#2 325 mg / QD / Oral
3. Therapy dates (if unknown, give duration)
#1 08/01/1999 - 01/16/2000
#2 -
4. Diagnosis for use (separate indications with commas)
#1 Pain; hip fracture
#2 Antiplatelet
5. Event abated after use stopped or dose reduced
#1 [X] yes [] no [] doesn't apply
#2 [X] 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)
Patient received 2 units of PRBC and pepcid. Other concomitant therapies are not known

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 device 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)

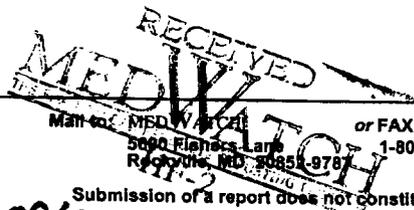
1. Name phone #
Hospital Pharmacy Department,
Street
United States
2. Health professional? [X] yes [] no Pharmacist
3. Occupation
4. Also reported to
[] manufacturer
[] user facility
[] distributor
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. [X]

DSS MAR - 3 2000

RECEIVED

MAR 02 2000

MEDWATCH CTU



Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20857-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500

CTU 118094

MAR 1 2000 10:48

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

Individual Safety Report



3470665-X-00-01

or VOLUNTARY reporting
y health professionals of adverse
events and product problems

Form Approved OMB No. 0710-0291 Exp. 12-31-02

FDA Use Only

FD-1089 (Rev. 11/99) 110962

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

CDER

A. Patient information

1. Patient Identifier XX In confidence	2. Age at time of event: 56y 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 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) **10-2-99**

4. Date of this report (m/d/yyyy) **3-7-00**

5. Describe event or problem (up to a total of 6400 characters allowed)

Gastrointestinal Bleeding: Melena. Patient with h/o gastritis came to hospital b/o melanic stools x 3 days with dizziness. 4 days PTA begun on naproxen for knee sprain. Unable to scope d/t patient's severe anxiety. Hgb/HCT=10/30. F/U in GI clinic. A/P from GI clinic F/U: UGIS most likely d/t NSAID induced ulcer. Later EGD wnl. **DCB 3 DAY PABWT**

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

DSS
MAR - 8 2000

7. Other relevant history, including preexisting medical conditions (up to a total of 800 characters allowed)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 NAPROXEN /	3. Therapy dates (if unknown, give duration) From To (or best est.)
2. Dose/Frequency/Route used #1 / /	#2 / /
4. Diagnosis for use (separate indications with commas) #1	5. Event abated after stopped or dose rec? #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/>
6. Lot # (if known) #1	7. Exp. date (if known) #1
8. NDC # (for product problems only)	9. Event reappeared on reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/>

10. Concomitant medical products and therapy dates (up to a total of 1000 characters allowed)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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

5. Expiration date (m/d/yyyy)

6. Model #

7. If implanted, giv (m/d/yyyy)

8. If explanted, giv (m/d/yyyy)

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

10. Concomitant medical products and therapy dates (up to a total of 1000 characters allowed)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____

Address _____ Med Center _____ E-mail (for electronic submission) _____
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.



Mail to: MEDWATCH
5800 Fishers Lane
Rockville, MD 20852-9747

or FAX to:
1-800-FDA-0178

CTU 118962



RECEIVED

MAR 07 2000
MEDWATCH CTU

Individual Safety Report



or VOLUNTARY reporting / health professionals of adverse events and product problems

Form Approved OMB No. 0910-0281 Expires See OMB statement on

FDA Use Only

FD-1089 (Rev. 11/97) FD-1089 (Rev. 11/97) 118371

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

COER

A. Patient information

1. Patient identifier: **XX**
In confidence

2. Age at time of event: **59y**
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 disability
 life-threatening congenital anomaly
 hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: **1-24-00**

4. Date of this report: **3-7-00**

5. Describe event or problem (up to a total of 6400 characters allowed)

Gastrointestinal Bleed: Melena. Patient came to Emer Room c/o generalized weakness x 3 weeks. Gots SOB w/ minimal exertion but no CP. Denies blood or black stools. No hematemesis or other bleeding. No medical HX except appendectomy when young. Took Naproxen + Aspirin 2 weeks ago for headache now resolved. BP=124/80, P=118, R=S2 settled to 20. Hbg=3.3, HCT=11.7. Pale. Rectal: dark, guaiac positive. DX: GI Bleed likely d/t NSAIDs. Treat: 2 u PRBC, Prevacid PO x 1. Admitted for FAU. **DC 5 Days p Admit**

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

DSS
MAR - 8 2000

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 **NAPROXEN /**
 #2 **ASPIRIN /**

2. Dose/Frequency/Routes used
 #1 / /
 #2 / /

3. Therapy dates (If unknown, give duration)
 #1 From - To (or best estimate)
 #2 - -

4. Diagnosis for use (separate indications with commas)
 #1
 #2

5. Event abated after us stopped or dose redi.
 #1 yes no dc
 #2 yes no dc

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

8. Event reappeared after reintroduction
 #1 yes no dc
 #2 yes no dc

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

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. RECEIVED
 model #
 catalog # **MAR 07 2000**
 serial # **MEDWATCH CTU**
 lot #

7. If implanted, give (mm/dd/yyyy)

8. If explanted, give (mm/dd/yyyy)

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

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

E. Reporter (see confidentiality section on back)

1. Name _____ phone _____

Address _____
 _____ Med Center
 _____ ST. RM _____

E-mail (for electronic acknowledgment) _____

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.

FDA Mail to: MEDWATCH 3800 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

MAR 07 2000 010 118371



3484085-5-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CDER FDA Use Only

Form Approved: OMB No. 0910-0281 Expires: 4/2000
See CDER statement on reverse

Trace unit
equivalent # **120015**

CDER

A. Patient information

1. Patient identifier YY In confidence	2. Age at time of event: 66yr 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 type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) **11-5-99**

4. Date of this report (mm/dd/yyyy) **4-4-00**

5. Describe event or problem (up to a total of 8400 characters allowed)

Gastrointestinal Bleed: Melena. Patient referred from rheumatology clinic for Anemia (Hgb=6.7). Has long H/O NSAID use (Naproxen). H/O PUD 8 yrs ago. Home stool positive. Given 4 u PRBC's. HCT 38.1. Final DX: Chronic GI Bleed prob d/t duodenitis d/t chronic NSAID use. On 9th HD, transferred to Orthopedics where had spine fusion.

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)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Naproxen / /	3. Therapy dates (if unknown, give duration) #1 From To (or best estimate)
2. Dose/Frequency/Route used #1 / /	#2 / /
4. Diagnosis for use (separate indications with commas) #1	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known) #1	7. Exp. date (if known) #1
8. Lot # (if known) #2	7. Exp. date (if known) #2
9. NDC # (for product problems only)	8. Event reappeared after reintroduction #1 <input 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

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address
DSS
APR 06 2000

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

5. Expiration date (mm/dd/yyyy)

6. RECEIVED
model #
catalog # **APR 05 2000**
serial #
lot # **MEDWATCH CTU**
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)

E. Reporter (see confidentiality section on back)

1. Name
phone #

Address
Med Center
St. RM

E-mail (for electronic acknowledgment)

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 20852-0787

or FAX to:
1-800-FDA-0178

CTU 120015

APR 11 2000 11:41



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

use by user-facilities,
distributors and manufacturers for
MANDATORY reporting.

APPROVED BY FDA ON 03/06/98

Mfr report # 203479

UF/Dist. report #

Page 1 of 2

FDA Use only

A. Patient Information

1. Patient identifier: NO INFO
In confidence

2. Age at time of event: UNK
Date of birth:

3. Sex: female
 male

4. Weight: UNK lbs
or
UNK 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 prolonge
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event: UNK / / (m/day/yr)

4. Date of this report: MAY / 10 / 2000 (m/day/yr)

5. Describe event or problem
 A FEMALE PATIENT (AGE UNKNOWN) WAS HOSPITALISED DUE TO RECTAL BLEEDING DURING THE USE OF NAPROSYN (NAPROXEN) FOR AN UNKNOWN INDICATION. THE PATIENT HAD A CERVICAL SPINE INJURY (DATE UNKNOWN) BUT NO OTHER MEDICAL HISTORY WAS REPORTED. IT WAS UNKNOWN WHETHER OR NOT THE PATIENT WAS TAKING ANY CONCOMITANT MEDICATION. UNKNOWN DATE. NAPROSYN THERAPY COMMENCED ORALLY (DOSAGE AND REGIMEN UNKNOWN). UNKNOWN DATES: THE PATIENT EXPERIENCED RECTAL BLEEDING AND WAS HOSPITALISED (NO INFORMATION WAS PROVIDED REGARDING THE COLOUR OF THE PATIENT'S STOOLS OR ABOUT THE PATIENT'S CONDITION UPON ADMISSION TO HOSPITAL). THE PATIENT RECEIVED 5 UNITS OF BLOOD. THE NAPROSYN THERAPY WAS DISCONTINUED. 25 MAR 99: AT THE TIME OF THE REPORT, THE REPORTING PHYSICIAN INDICATED THAT THE RECTAL BLEEDING WAS ATTRIBUTABLE TO THE NAPROSYN THERAPY. NO TESTS HAD BEEN PERFORMED TO RULE OUT THE POSSIBILITY OF CANCER, ALCOHOL ABUSE OR IRRITABLE BOWEL SYNDROME. THE PATIENT WAS STILL

CONTINUED

6. Relevant tests/laboratory data, including dates
 UNK

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

Medical History Terms
 SPINAL INJURY

Medical History Text
 IT WAS UNKNOWN WHETHER OR NOT THE PATIENT WAS TAKING ANY CONCOMITANT MEDICATION.

CC. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 NAPROSYN (NAPROXEN)
 #2 NA

2. Dose, frequency & route
 #1 ORAL
 #2 NA

3. Therapy dates (if unk, give duration) from to (or best estimate)
 #1 UNK
 #2 NA

4. Diagnosis for use (indication)
 #1 UNKNOWN
 #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 UNK
 #2 NA

7. Exp. date (if known)
 #1 UNK
 #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)
 #1 NA #2 NA

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

G. All manufacturers

1. Contact Office-name/address (& mfring site for devices)
 GLOBAL DEVELOPMENT
 HOFFMANN-LA ROCHE INC.
 340 KINGSLAND STREET
 NUTLEY, NJ 07110-1199

2. Phone Number
 (973) 562-3523

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

4. Date received by manufacturer (m/day/yr)
 MAR / 25 / 1999

5. (A)NDA# 17-581
 IND #
 PLA #
 pre-1938 yes
 OTC product yes

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

8. Adverse event term(s)
 RECTAL BLEEDING +++

9. MFR report number
 203479

MAY 1 1 2000

+++ adverse event that generated submission

E. Initial reporter

1. Name, address & phone #
 DR. [REDACTED]
 [REDACTED]
 UNITED STATES OF AMERICA

2. Health professional?
 yes no

3. Occupation
 DOCTOR OF MEDICINE

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

CONTINUED



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



CONTINUATION SHEET FOR FDA-3500A FORM
ROCHE

Mfr report # 203479

Page 2 of 2

B.5. Describe event or problem - continued

IN HOSPITAL AND THE RECTAL BLEEDING WAS
PERSISTING.
NO FURTHER INFORMATION WAS PROVIDED.

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: [REDACTED]

MAY 11 2000



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting.

APPROVED BY FDA ON 03/06/98

Mfr report # 226735

UF/Dist. report #

Page 1 of 2

FDA Use only

A. Patient information

1. Patient Identifier	2. Age at time of event: 79 YEARS	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 179.9 lbs 81.6 kgs
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In confidence

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> 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"/> life threatening <input checked="" type="checkbox"/> hospitalization initial or prolonge <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) / / 1997 E	4. Date of this report (mo./day/yr) MAY / 10 / 2000

5. Describe event or problem
 A 79 YEAR OLD FEMALE PATIENT WAS HOSPITALISED FOR A HAEMORRHAGIC ULCER DURING THE USE OF NAPROSYN (NAPROXEN) FOR ARTHRITIS/BACK PAIN RELIEF.

THE PATIENT HAS A MEDICAL HISTORY OF HIGH BLOOD PRESSURE. SHE DOES NOT SMOKE OR DRINK ALCOHOL, AND HAS NO KNOWN ALLERGIES. SHE REPORTS HAVING NO PREVIOUS HISTORY OF PEPTIC ULCERATION. 1987 (EST): NAPROSYN THERAPY WAS STARTED, PO (UNKNOWN DOSE/REGIMEN). THE PATIENT REPORTS TAKING NAPROSYN ON A DAILY BASIS WITHOUT EXPERIENCING ANY ADVERSE REACTIONS. 1997 (EST): THE PATIENT WAS HOSPITALISED FOR TWO WEEKS DUE TO A BLEEDING ULCER. SHE EXPERIENCED BLEEDING FROM THE RECTUM AND EPISODES OF VOMITING BLOOD, FOR WHICH SHE RECEIVED TWO UNITS OF BLOOD. DATES UNKNOWN: NAPROSYN THERAPY WAS STOPPED, AND THE PATIENT RECOVERED FROM THIS EVENT. THE REPORTER WAS THE PATIENT.

6. Relevant tests/laboratory data, including dates
 UNK

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

Medical History Text
 THE PATIENT DOES NOT SMOKE OR DRINK ALCOHOL, AND HAS NO KNOWN ALLERGIES

CC Suspect medication(s)

1. Name (give labeled strength & mfr./labeler, if known) #1 NAPROSYN (NAPROXEN) #2 NA	2. Dose, frequency & route #1 ORAL #2 NA	3. Therapy dates (if unk. give duration) from/to (or best estimate) #1 15-JUN-1987 E / 15-JUN-1997 E #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
4. Diagnosis for use (indication) #1 ARTHRITIS #2 NA	6. Lot # (if known) #1 UNK #2 NA	7. Exp. date (if known) #1 UNK #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) #1 NA #2 NA		10. Concomitant medical products and therapy dates (exclude treatment of event) ANTIHYPERTENSIVE NOS CONTINUING (ANTIHYPERTENSIVE NOS)	

G. All manufacturers

1. Contact Office-name/address (& mfrng site for devices) GLOBAL DEVELOPMENT HOFFMANN-LA ROCHE INC. 340 KINGSLAND STREET NUTLEY, NJ 07110-1199	2. Phone Number (973) 562-3523	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) JAN / 21 / 2000	5. (A)NDA# 17-581 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	
6. If IND, protocol # NA		
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 type="checkbox"/> initial <input type="checkbox"/> follow-up <input type="checkbox"/> #	8. Adverse event term(s) HAEMORRHAGIC ULCER +++ -RECTAL BLOOD LOSS -HAEMATEMESIS	

9. MFR. report number
226735

+++ adverse event that generated submission - comanifestation

E. Initial reporter

1. Name, address & phone #
 STREET
 UNITED STATES OF AMERICA

MAY 11 2000

CONTINUED

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation N/A	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.

E-Indicates estimated date, P-Indicates partial date



3499643-1-00-02

CONTINUATION SHEET FOR FDA-3500A FORM
ROCHE

Mfr report # 226735

Page 2 of 2

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: [REDACTED]

MAY 11 2000



3505361-3-00-01

VOLUNTARY reporting
with professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 3/31/0
See OMB statement on revers

FDA Use Only
Triage unit
sequence #

CDER 123179

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

CDER

1. Patient identifier: 017-062-
 2. Age at time of event: _____
 or _____
 Date of birth: _____
 In confidence

3. Sex: female male

4. Weight: _____ lbs or _____ kgs

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): 5/3/00
 4. Date of this report (m/day/yr): 5/22/00

Describe event or problem

Started on prednisone 5mg QD 5/1/00 for "pinched sacraliic." Admitted to the hospital 5/3/00 for severe abdominal pain. The doctors initially suspected ovarian cancer. However, at surgery on 5/10/00, there was no evidence of malignancy, but rather a perforated jejunal ulcer with peritonitis. The involved segment of intestine was resected.

The subject went into rehabilitation on 5/17/00 and is doing well. She is expected to remain there for at least two weeks.

6. Relevant tests/laboratory data, including dates

RECEIVED
 MAY 26 2000
 MEDWATCH CTU

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

Occasional stomach pain, but not present at baseline or 1 month visit.
 Low energy reported at baseline visit on 3-22-00

1. Name (give labeled strength & ml/rlabeler, if known)
 #1 rofecoxib 25mg po qd or
 #2 naproxen 200mg po bid or placebo

2. Dose, frequency & route used

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

4. Diagnosis for use (indication)
 #1 Alzheimer's disease

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)

8. Event reappeared after reintroduction

9. NDC # (for product problems only)

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

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)

1. Name & address phone #

DEPT NEUROLOGY MD
MED C

2. Health professional? 3. Occupation 4. Also reported to

yes no PHYSICIAN 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

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



MEDWatch

Approved by FDA on 10/20/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

Triage unit sequence # 123656

CDER

Page 1 of 2

A. Patient Information

C. Suspect Medication(s)

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight
[REDACTED] | AGE: 66 yrs | MALE | 98.0 kg

1. Name
#1 : NAPROXEN

B. Adverse Event or Product Problem

#2 : ASPIRIN 81MG EC TAB Vitamin E

1. [X] 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: | #1:
#2: | #2:
4. Diagnosis for use (indication) | 5. Event abated after use
stopped or dose reduced?
#1: | #1: [N/A]
#2: | #2: [N/A]

3. Date of event | 4. Date of this report
04/19/00 | 04/19/00

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after
reintroduction
#1: | #1: []
#2: | #2: []

5. Describe event or problem
GI BLEED

RECEIVED

JUN 06 2000

MEDWATCH CTU

(Not applicable to adverse drug event reports)

6. Relevant test/laboratory data, including dates

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

DSS

JUN - 7 2000

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]

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

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

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

FDA Form 3500

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

CTU123656



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: [redacted]	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 (mo/day/yr) _____

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

5. Describe event or problem

Self medicated w/ Naprosyn, Motrin, ASA for pain. Black, continued melena 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 and tobacco use, hepatic/renal dysfunction, etc.):

C. Suspect medication(s)

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

#1 **Naprosyn**

#2 **MOTRIN, ASPIRIN**

2. Dose, frequency & route used

#1 _____

#2 _____

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

#1 _____

#2 _____

4. Diagnosis for use (indication)

#1 **PAIN**

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no do not apply

#2 yes no do not apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no do not apply

#2 yes no do not 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)

6. model # _____

catalog # **JUL 18 2000**

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

CTU 125818



3530458-1-00-01

health professionals of adverse events and product problems

Page ___ of ___

CDER CDER

FDA Use Only

Trace unit sequence #

See OMB statement on...

125824

A. Patient Information

1. Patient identifier in confidence [redacted]	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 ____ 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): 4/13/00

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

5. Describe event or problem

Pt admitted for UGI bleed 2^o to high NSAID use over 2 months. Start Prevacid.

6. Relevant tests/laboratory data, including dates

RECEIVED
JUL 17 2000
MEDWATCH CTU

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/ratiobaler, if known)

#1 Naproxen

#2 _____

2. Dose, frequency & route used

#1 1 GM/day

#2 _____

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

#1 1 month

#2 _____

4. Diagnosis for use (indication)

#1 arthritic 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

DSS

JUL 18 2000

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] Blac

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.

CTU 125824



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

or FAX to:
1-800-FDA-0178



CDER

Form Approved: OMB No. 0910-0291
FDA Use Only

MEDWATCH

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

Triage unit sequence #	126043
CDER	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event 76 or DOB:	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			
2. Outcomes attrib. to event <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm impair/damage <input type="checkbox"/> other:	
3. Date of event 07/10/1999		4. Date of this Rept 11/19/1999	
5. Describe event or problem Upper GI bleed with vomiting of blood. H/H decreased to 11.4 / 35.3. EGD revealed distal esophageal ulcer which was treated with epinephrine injections and banding			
6. Relevant tests/laboratory data, including dates DSS JUL 24 2000			
7. Other relevant history, including preexist. med. conditions			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known): #1 Naproxen and ASA			
2. Dose, frequency & route #1		3. Therapy dates (if unk, give dur) #1	
4. Diagnosis for use (indication) #1		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1		7. Exp. Date #1	
9. NDC # for prod problems only #1		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
10. Concomitant medical products and therapy dates			
D. SUSPECT MEDICAL DEVICE			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of Dev. <input type="checkbox"/> Hlth Profes. <input type="checkbox"/> lay user/pat. <input type="checkbox"/> other:	
6. Model# catalog# serial# lot# other#		5. Expiration Date	
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to mfr on		7. If implanted, give date	
10. Concomitant medical products and therapy dates		8. If removed, give date	
E. INITIAL REPORTER			
1. Name, address & phone # VA Medical Center 3200 Vine Street Cincinnati, OH 45220			
2. Health profess.? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Pharmacist	
5. If you do NOT want your identity disclosed to the Mfr, place an 'X' in box <input checked="" type="checkbox"/>		4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	

MED INFO ASSOC Mail MedWatch or FAX to:
 Facsimile to: 5600 Fishers Lane 1-800-FDA-0178
 Rockville, MD 20852-9787
 Submission of a report does NOT constitute an admission that medical personnel or the product caused or contributed to the event.

CDU 126043



Patient information

1. Patient identifier: [redacted]

2. Age at time of event: 80

3. Sex: Female Male

4. Weight: 125 lbs

5. Date of Birth: [redacted]

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

direct

6. Date of event: 2/15/00

7. Date of this report: 2/16/00

Describe event or problem

At presented with two day H/o hematochezia. NG lavage ⊕. Colonoscopy. Admitted to floor → tx to ICU for continued bleeding. Underwent angiogram for continued bleeding. Tx 1 unit PRBCs. Naprosyn Δ to persceet.

Relevant tests/laboratory data, including CAES

12/99 Hct 40

2/15/00 Hct ~~38~~ 38

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

HTN, DM, OA, diverticulosis, BPH, prostate CA.

Severity: severe Probability: probable

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

or FAX to: 1-800-FDA-0178

FDA CTU 127435

C. Suspect medication(s)

1. Name (give labeled strength & ml/caps or if known): naprosyn

2. Dose, frequency & route used: pm

3. Therapy dates if unknown, give date of start/stop:

4. Diagnosis for use (indication): OA

5. Event abated after use stopped or dose reduced: Yes No Yes No Yes No

6. Event reappeared after reintroduction: Yes No Yes No Yes No

7. NDC # (for product problems only):

8. Concomitant medical products and therapy dates (include 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 (if any):

6. If implanted, give C (if any):

7. If implanted, give C (if any):

8. If implanted, give C (if any):

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

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] Pharm D DSS
Baltimore VAMC
10 North Greene Street
Baltimore, Maryland 21201

2. Health professional? yes no

3. Occupation: Clinical Pharmacist

4. Also reported to: manufacturer user/patient distributor

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

281021

ADR Probability Scale

(Naranjo, CA et al. CPT 1981;30:239-45)

To assess the adverse drug reaction, please answer the following questionnaire and 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:

MEDWATCH
 THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report #	235107
UF/Diet. report #	
FDA Use only	

A. Patient information

1. Patient identifier [REDACTED]	2. Age at time of event: or 23 YEARS Date of birth: [REDACTED]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 110 lbs or 49.9 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 prolonge	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event: DEC / / 1981 E
 4. Date of this report: SEP / 22 / 2000

5. Describe event or problem

A 23 YEARS OLD MALE PATIENT EXPERIENCED AGGRAVATED CROHN'S DISEASE REQUIRING INTERVENTION DURING THE USE OF ACCUTANE (ISOTRETINOIN) FOR SEVERE CYSTIC ACNE.

THE PATIENT'S FATHER ALSO HAD CYSTIC ACNE AND WAS TREATED WITH X-RAYS. THE PATIENT WAS TAKING CONCOMITANT MEDICATION OF VIBRAMYCIN (DOXYCYCLINE) PO (DOSE AND REGIMEN UNSPECIFIED) AND PO PREDNISONE 15MG/DAY.

NOV 1981 (EXACT DATE UNKNOWN): THE PATIENT COMMENCED A 16-18 WEEK COURSE OF ACCUTANE THERAPY WHICH VARIED FROM 40-80MG/DAY.

NOV 1981 (EXACT DATE UNKNOWN): THE PATIENT EXPERIENCED A FLARE-UP OF CROHN'S DISEASE WITH CONSISTENT ABDOMINAL PAIN, WEIGHT LOSS AND DIARRHOEA.

FEB 1982 (EXACT DATE UNKNOWN): ACCUTANE THERAPY STOPPED.

MAY 1982 (EXACT DATE UNKNOWN): THE EVENT RESOLVED.

MAY 1983 (EXACT DATE UNKNOWN): THE PATIENT RECOMMENCED ACCUTANE THERAPY (DOSE AND REGIMEN

6. Relevant tests/laboratory data, including dates

HEMATOCRIT
 1989-1991: FALLING HAEMOGLOBIN (VALUES UNSPECIFIED).

HEMATOCRIT
 1989-1991: FALLING HEMATOCRIT (VALUES UNSPECIFIED).

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

Medical History Terms
 CROHN'S DISEASE SEP-1979 E

SEP 25 2000

C. Suspect medication(s)

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

#1 NAPROXEN SODIUM (NAPROXEN SODIUM)

#2 ACCUTANE CAPSULES (ISOTRETINOIN)

2. Dose, frequency & route

#1 UNK

#2 40 MG DAILY ORAL

3. Therapy dates (if unk. give duration)

#1 UNK

#2 15-NOV-1981 E / 15-OCT-1983 E

4. Diagnosis for use (indication)

#1 UNKNOWN

#2 CYSTIC ACNE

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 (if known)

#1 NA #2 NA

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

VIBRAMYCIN UNK / 15-DEC-1981 E (DOXYCYCLINE)

PREDNISONE UNK (PREDNISONE)

G. All manufacturers

1. Contact Office-name/address

GLOBAL DEVELOPMENT
 HOFFMANN-LA ROCHE INC.
 340 KINGSLAND STREET
 NUTLEY, NJ 07110-1199

2. Phone Number
 (973) 562-3523

3. Report source (check all that apply)

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

4. Date received by manufacturer
 SEP / 12 / 2000

5. (A)NDA# 18-164
 IND #
 PLA #
 pre-1938 yes
 OTC yes
 product yes

6. If IND, protocol #
 NA

7. Type of report (check all that apply)

5 - day 15 - day
 10 - day periodic
 initial follow-up #

8. Adverse event term(s)

CROHN'S DISEASE AGGRAVATED +++
 -ABDOMINAL PAIN
 -WEIGHT LOSS
 -DIARRHOEA
 -GASTROINTESTINAL BLEEDING
 -HAEMATOCRIT LOW
 -HAEMOGLOBIN LOW
 +++ adverse event that generated submission -comanifestation

9. MFR. report number
 235107

E. Initial reporter

1. Name, address & phone #

[REDACTED]

SEP 26 2000

UNITED STATES OF AMERICA

2. Health professional?
 yes no

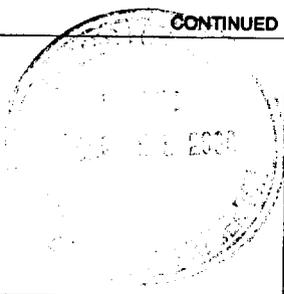
3. Occupation
 N/A

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.

E-Indicates estimated date or dose, P-Indicates partial date



CONTINUED

**B.5. Describe event or problem - continued**

UNSPECIFIED) FOR 16-18 WEEKS.

JUN 1983 (EXACT DATE UNKNOWN): THE PATIENT EXPERIENCED A FURTHER FLARE-UP OF CROHN'S DISEASE, AGAIN WITH CONSISTENT ABDOMINAL PAIN, WEIGHT LOSS AND DIARRHOEA.

OCT 1983 (EXACT DATE UNKNOWN): ACCUTANE THERAPY STOPPED.

DATE UNKNOWN: THE PATIENT UNDERWENT UNSPECIFIED SURGERY FOR CROHN'S DISEASE.

EARLY 1990'S (EXACT DATE UNKNOWN): THE EVENT RESOLVED.

APR 00 (APPROX.): THE PATIENT STATED THAT HE WAS EXPERIENCING A SEVERE ACNE BREAKOUT AND WAS THINKING ABOUT ASKING HIS PHYSICIAN FOR A PRESCRIPTION FOR ACCUTANE AGAIN.

THE REPORTER, WHO WAS THE PATIENT, STATED THAT DURING THE 2 OCCASIONS THAT HE TOOK ACCUTANE, THE SYMPTOMS OF CROHN'S DISEASE WERE IN REMISSION, BUT WOULD FLARE 1 MONTH AFTER COMMENCING ACCUTANE THERAPY. HE ALSO STATED THAT AFTER THE SECOND EPISODE, THE SYMPTOMS CONTINUED LONG AFTER DISCONTINUING ACCUTANE. THE COMPANY ASSESSED THE EVENT OF CROHN'S DISEASE AS MEDICALLY SIGNIFICANT.

FURTHER INFORMATION WAS RECEIVED ON 12 SEP 2000 WHICH INDICATED GASTROINTESTINAL BLEEDING, LOW HAEMATOCRIT AND LOW HAEMAOGLOBIN AS COMANIFESTATIONS OF CROHN'S DISEASE. NAPROXEN SODIUM WAS ADDED AS A SECOND SUSPECT DRUG.

THE PATIENT EXPERIENCED SYMPTOMS OF CROHN'S DISEASE IN THE FALL OF 1979 AND WAS DIAGNOSED WITH CROHN'S DISEASE IN FEB 1980 USING COLONOSCOPY.

DATE UNKNOWN: NAPROXEN SODIUM (DOSE AND ROUTE AND INDICATION UNSPECIFIED) WAS STARTED. A COUPLE OF DAYS LATER, HIS SYMPTOMS OF CROHN'S DISEASE FLARED-UP.

DEC 1981 (EST): AFTER A MONTH OF STARTING ACCUTANE, HIS SYMPTOMS OF CROHN'S DISEASE FLARED-UP.

DATE UNKNOWN: THE PATIENT BLAMED HIS SYMPTOMS OF CROHN'S DISEASE ON NAPROXEN WHICH WAS STOPPED.

MAR 1982 (EST): THE SYMPTOMS OF CROHN'S DISEASE SUBSIDED.

MAY 1983: ACCUTANE WAS RESTATED AT 40 MG DAILY. TREATMENT WITH PREDNISOLONE 15 MG DAILY WAS CONTINUED.

JUN 1983 (EST): THE SYMPTOMS OF CROHN'S DISEASE RECURRED.

1987 (EST): FOUR YEARS AFTER THE LAST THERAPY WITH ACCUTANE, THE PATIENT WAS HOSPITALISED. HE RECEIVED TOTAL PARENTERAL NUTRITION AND IV STEROIDS (UNSPECIFIED).

AUG 1987: THE PATIENT UNDERWENT AN UNSPECIFIED SURGERY.

1989-1991: THE PATIENT RECEIVED MULTIPLE TRANSFUSION DUE TO INTERNAL BLEEDING AND FALLING HAEMOGLOBIN AND HEAMTOCRIT (VALUES UNSPECIFIED).

JAN 1992: THE PATIENT UNDERWENT ILEOSTOMY.

THE PATIENT STATED THAT ACCUTANE WAS POSSIBLY RESPONSIBLE FOR CROHNS DISEASE FLARE-UPS BECAUSE THEY HAPPENED BOTH TIMES AFTER STARTING ACCUTANE. HE ALSO STATED THAT HIS SYMPTOMS RECURRED AND RESOLVED WHICH IS TYPICAL OF CROHNS DISEASE. HIS LAB WORK WAS NOW NORMAL. THE ACCUTANE THERAPY GREATLY IMPROVED HIS CYSTIC ACNE, BUT THE CORTICOSTEROIDS CAUSED HIS CYSTIC ACNE TO RECUR.

C.1. thru C.9. Suspect medication(s) - continued

Suspect medication #2

G5. NDA #, IND #, PLA #, OTC

NDA #: 18-662

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: XXXXXXXXXX

DSS

SEP 25 2000

SEP 26 2000



3580578-0-00-01

by health professionals of adverse events and product problems

Page 1 of 1

QDER

CADER

Trace unit sequence #

129467

1. Patient identifier 2. Age at time of event: 82 3. Sex female male 4. Weight _____ lbs or _____ kgs
 or _____ Date of birth: _____
 In confidence

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) approx 8/31/00 4. Date of this report (mo/day/yr) 9/15/00

5. Describe event or problem
 The subject developed abdominal pain, and an evaluation was initiated by her primary physician. She was found to have guaiac positive stool, and abdominal CT showed duodenal ulcer. While this evaluation was in progress, she visited an ER on 9/10 complaining of shoulder pain, and was treated with a 3 day course of Vicxx 25mg. Abdominal pain worsened on 9/14, and on that day study medication was discontinued, and treatment was initiated with Prilosec, Flagyl, and Cipro. She was hospitalized on 9/15 for abdominal pain. Laboratory studies revealed stable hematocrit but ~~evaluated~~ elevated creatinine. The creatinine rose to about 4, and then stabilized.

⊛ Event still in progress ⊛

6. Relevant tests/laboratory data, including dates

RECEIVED
 SEP 26 2000
 MEDWATCH CTU

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

No previous ulcers

1. Name (give labeled strength & mfr/labeled, if known)
 #1 rofecoxib 25mg po qd OR
 #2 naproxen 200mg po bid OR placebo
 2. Dose, frequency & route used 3. Therapy dates (if unknown, give duration) from/to (or best estimate)
 #1 #1
 #2 #2
 4. Diagnosis for use (indication)
 #1 Alzheimer's disease
 #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)
 - -
 10. Concomitant medical products and therapy dates (exclude treatment of event)

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) DSS
 model # _____
 catalog # _____ SEP 27 2000
 serial # _____
 lot # _____
 7. If implanted, give date (mo/day/yr)
 8. If explanted, give date (mo/day/yr)
 other # _____

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)

1. Name & address phone # _____
 _____, MD
 Department of Neurology, _____ Building

2. Health professional? 3. Occupation 4. Also reported to
 yes no Physician manufacturer
 user facility
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. distributor



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

CTU 129467

Individual Safety Report



3588538-0-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

VOLUNTARY reporting health professionals of adverse events and product problems

Internet Submission - Page 1

Form Approved: OMB No. 0918-0291 Expires: 11/30/00 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

130377

A. Patient information

1. Patient Identifier, 2. Age at time of event: 58 Years, 3. Sex: male, 4. Weight: 184 lbs

B. Adverse event or product problem

1. Adverse event and/or Product problem, 2. Outcomes attributed to adverse event

3. Date of event: 06/30/2000, 4. Date of this report: 10/03/2000

5. Describe event or problem: 58 year old male seen in UCC on 6/30/00. Patient had been taking both indomethacin and naproxen...

6. Relevant tests/laboratory data, including dates: RECEIVED OCT 05 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 (Product Name) (Labeled Strength) (Mfr/Labeler): NAPROXEN, INDOMETHACIN, 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 and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name: DSS, 2. Type of device, 3. Manufacturer name & address, 4. Operator of device, 5. Expiration date: OCT 05 2000, 6. model #, catalog #, serial #, lot #, 7. If implanted, give date, 8. If explanted, give date, 9. Device available for evaluation?

E. Reporter (see confidentiality section on back)

1. Name, phone #, VAMC SAN DIEGO, 3350 LA JOLLA VILLAGE DR, SAN DIEGO, California 92161, 2. Health professional? yes, 3. Occupation: Physician, 4. Also reported to: user facility, 5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



FDA Form 3500

Mail to: MEDWATCH, 5800 Fishers Lane, Rockville, MD 20857-9782 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 130377



o Wellcome

Approved by the FDA (HF-2) on 3 Nov 93

Mfr report #	A0121575A
UF/Out report #	
FDA Use Only	

(Page 1 of 3)

A. Patient information			
1. Patient identifier 	2. Age at time of event: 26Y or Date of birth UNK	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male <input type="checkbox"/> unknown	4. Weight (lb) UNK
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death	<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 type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> other: _____		
3. Date of event: UNK	4. Date of this report: 20Sep2000		
5. Describe event or problem A 26 year old male reported that he received lamivudine/zidovudine (Combivir) tablets for treatment of HIV during the past three years. He developed vomiting and noticed blood in the vomit after approximately one month of receiving concurrent medications, semisodium valproate and naproxen. Semisodium valproate and naproxen were discontinued and the events resolved.			
6. Relevant tests/laboratory data, including dates UNK			
7. Other relevant history, including preexisting medical conditions (eg. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) See attachment			

C. Suspect medication(s)		
1. Name (give labeled strength & mfr/labeler, if known) cont'd next page		
#1	Combivir Tablet (Combivir)	
#2	Semisodium valproate (formulation unknown) (Divalproex sodium)	
2. Dose / frequency / route used		3. Therapy dates
#1	UNK / UNK / Oral	#1 3 Years
#2	UNK / UNK / Unknown	#2 May00 - Jun00
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced
#1	Human immunodeficient virus	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	UNK	#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)	8. Event reappeared after reintroduction
#1 None	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 None	#2	#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) UNK		

G. All manufacturers	
1. Contact office - name/address Glaxo Wellcome North American Product Surveillance PO Box 13398 Research Triangle Park NC 27709	2. Phone number 1-888-825-5249 ext. 37070
3. Report source <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 01Jun2000	5. (A)NDA # 20-857
6. If IND, protocol #	IND # _____ PLA # _____
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 # _____	pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes
9. Mfr. report number A0121575A	8. Adverse event term(s) Vomiting Hematemesis

E. Initial Reporter			
1. Name, address & phone # Consumer USA			SEP 25 2000
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation UNK	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.



3591204-9-00-03

Wellcome

(page 3 of 3)

Approved by the FDA on 3Nov93

Mfr report #	A0121575A
UF/Dist report #	
FDA Use Only	

B7. Other relevant history (cont'd)

Condition	Started	Ended	Continuing
HIV	Unknown	Unknown	Yes

SEP 25 2000



Form 3500A Facsimile

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



3601250-4-00-01

VOLUNTARY reporting
 health professionals of adverse
 events and product problems

CDER

Form Approved: OMB No. 0910-0291 Expires 12/31/04
 See OMB statement on reverse

FDA Use Only H Pad
 Triage unit sequence # 131500

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___ CDER

A. Patient information

1. Patient identifier <u>00-88</u> In confidence	2. Age at time of event: or Date of birth: <u>[redacted]</u>	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight <u>185</u> 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) 07/19/2000

4. Date of this report (mo/day/yr) 10/04/2000

5. Describe event or problem

Pt. presented to ER when had black stool and c/o weakness and was unable to stand. In ER, pt. had one episode of hematemesis. On admission, Hemoglobin = 6.6 and Hematocrit = 19.8. Pt. thought to have upper GI bleed 2° to NSAID vs. Coumadin use. Coumadin and Naprosyn D/C'd. Pt. given Fresh frozen plasma. Pt. now being tx. w/ Fragmin for DVT.

6. Relevant tests/laboratory data, including dates

7/19/00: HGB = 7.8, HCT = 23.1
 7/24/00: HGB: 10.5, HCT = 31.3
 7/19/00: INR = 2.83, PT = 37.2
 7/23/00: INR = 1.18, PT = 12.7

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

Gastric CA (metastatic), Hypercholesterolemia, Glaucoma, Basal Cell CA, DVT

CTU131500

C. Suspect medication(s)

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

#1 Coumadin

#2 Naprosyn

2. Dose, frequency & route used

#1 5mg Alternating with 7.5 mg PO QD

#2 PRN

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

#1 PTA

#2 PTA

4. Diagnosis for use (indication)

#1 DVT

#2 Fever

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 unknown

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)

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

Reglan, Ambien, Lipitor

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
OCT 25 2000

4. Operator of device

health professional
 lay user/patient
 other: _____

5. Expiration date (mo/day/yr)

6. model # MEDWATCH CTU

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)

DSS
OCT 26 2000

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] Hospital
[redacted] Ave.
[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



COVANCE
by user - facilities distributors and
retailers for MANDATORY reporting

FDA Facsimile Approval 9/13/98

Mfr report #	7757040
UF/Dist report #	
FDA Use Only	

Page - 1 - of 1

A. Patient information

1. Patient identifier 7757040 In confidence	2. Age at time of event: 74 Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 210 lbs or kg
---	---	---	----------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g. defect or malfunction)

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"/> other: <u>Medically Significant</u>

3. Date of event (mo/day/yr) 08/16/2000

4. Date of this report (mo/day/yr) 11/27/2000

5. Describe event or problem

Information has been received from a 74-year-old male consumer who had taken 1 tablet of Aleve daily for cold symptoms from 08/14/00 to 08/16/00. On 08/16/00 the consumer developed a severe bloody nose. He reported that the nose bleeding continued for 1 hour and subsided after it was cauterized. Concomitant therapy included calcium supplement, allopurinol, Pepcid, hydrochlorothiazide, Nadolol, Univas, and Fosamax. Medical history included kidney stones, hypertension, seasonal allergies, and allergies to penicillin and amoxicillin. In addition, the consumer experienced melena during past use of Aleve. (Reference: case # 7599670). No additional information is expected.

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.)

History of kidney stones, high blood pressure, seasonal allergies, and allergy to penicillin and amoxicillin. Also experienced melena during the use of Aleve in the past (case # 7599670).

C. Suspect medication(s)

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

#1 ALEVE. Tablets - Any Type

#2

2. Dose, frequency & route used

#1 1 ORAL 01X/D

#2

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

#1 08/14/2000 - 08/16/2000

#2

4. Diagnosis for use (indication)

#1 Cough/Cold Symptoms

#2

5. Event abated after use stopped or dose reduced

#1 yes no n/a

#2 yes no n/a

6. Lot # (if known)

#1 UNK

#2

7. Exp. date (if known)

#1 UNK

#2

8. Event reappeared after reintroduction

#1 yes no n/a

#2 yes no n/a

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

#1

#2

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

Calcium supplement, allopurinol, Pepcid, hydrochlorothiazide, Nadolol, Univas, Fosamax

G. All manufacturers

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

Bayer Corporation
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

2. Phone number (973) 254-5000

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) 09/22/2000

5. (A)NDA # 20-204

IND #

PLA #

pre-1938

OTC product

8. Adverse event term(s) EPISTAXIS

9. Mfr. report number 7757040

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional? yes no

3. Occupation UNK

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.

NOV 30 2000



Approved by FDA on 11/19/99

Mfr report # _____

UDI/Dist report # _____

FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ____ of ____

A. Patient information				C. Suspect medication(s)			
1. Patient identifier In confidence	2. Age at time of event: or 72 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified Motrin (ibuprofen) Product #2 unspecified NAPROSYN® product			
B. Adverse event or product problem				2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
				#1 unknown dose, po #2 unknown dose, po		#1 unknown dates or duration #2 unknown dates or duration	
1. X Adverse event and/or Product problem (e.g., defects/ malfunctions)				4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
2. Outcomes attributed to adverse event (check all that apply)				#1 unknown #2 unknown		#1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
() death (mo/day/yr)				#1 unknown #2 unknown		#1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
() life-threatening							
() hospitalization - initial or prolonged				6. Lot # (if known)		7. Exp. date (if known)	
(X) other: none				#1 unknown #2 unknown		#1 unknown #2 unknown	
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 05/30/00		9. NDC # - for product problems only (if known)			
5. Describe event or problem				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
Consumer report received via other manufacturer of GASTROINTESTINAL DISORDER (gastroesophageal reflux disease) and RECTAL HEMORRHAGE (rectal bleeding) allegedly associated with unspecified MOTRIN® (ibuprofen) product or an unspecified NAPROSYN® product. No further information was provided.				G. All manufacturers			
6. Relevant tests/laboratory data, including dates unknown				1. Contact office - name/address (& mfring site for devices)		2. Phone number	
				McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		215-273-7303	
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) 05/26/00		3. Report source (check all that apply)	
				6. If IND, protocol #		() foreign () study () literature (X) consumer	
8. Adverse event term(s) GI DISORDER HEM RECTAL				7. Type of report (check all that apply)		() health professional () user facility	
				() 5-day () 15-day () 10-day (X) periodic (X) initial () follow-up #		() company representative () distributor () other:	
9. Mfr. report number 1369828A				5. (A) NDA # 17-463 IND # PLA # pre-1938 () Yes OTC product () Yes			
E. Initial reporter				8. Adverse event term(s) GI DISORDER HEM RECTAL			
1. Name, address & phone #				1. Name, address & phone #			
Gersha S. Kelly Wyeth-Ayerst Research P.O. Box 8299 Philadelphia, PA 19101				610-971-5400			
2. Health professional? () Yes () No		3. Occupation		4. Initial reporter also sent report to FDA () Yes () No (X) Yes			



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

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DEC 1 2000

Individual Safety Report



134109

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CDER

CSEL

Form # FD-1085 (Rev. 02/19/03) See OMB statement

FDA Use Only

Triage unit assignment #

A. Patient information

1. Patient identifier: **XX** In confidence

2. Age at time of event: **36y** 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 (mm/dd/yyyy): **9-15-00**

4. Date of this report (mm/dd/yyyy): **12-13-00**

5. Describe event or problem (up to a total of 8400 characters allowed)

GASTROINTESTINAL BLEED: HEMATEMESIS. Patient taking Naproxen BID w/ h/o H. pylori gastritis admitted to hospital b/o hematemesis x2. Hgb 13.7, VSS, not orthostatic. In hospital HCT remained stable, & no further episodes of hematemesis. Hematemesis believed d/t patient's increased NSAID use.

DISCHARGED 1 DAY P ADMITTED.

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
DEC 14 2000

CTV134109



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

or FAX to: 1-800-FDA-0888



C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)

#1 **NAPROXEN** / /

#2 / /

2. Dose/Frequency/Route used

#1 / / /

#2 / / /

3. Therapy dates (if unknown, give duration)

#1 From To (or best estimate)

#2 From To

4. Diagnosis for use (separate indications with commas)

#1

#2

5. Event abated after stopped or dose reduced?

#1 yes no

#2 yes no

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction?

#1 yes no

#2 yes no

9. NDC # (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (up to a total of 1000 characters allowed)

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 (mm/dd/yyyy)

8. If explanted, give (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 allowed)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____

Address _____

Med Center _____ St. Rd _____

E-mail (for electronic acknowledgment) _____

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.

DEC 14 2000

RECEIVED

Individual Safety Report



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems

Page ___ of ___

OVER

For Use Only	
Triage unit sequence #	134598

A. Patient information

1. Patient identifier 4509392 in confidence	2. Age at time of event: 87 or Date of birth: [redacted]	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):
 death (mortality)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (m/d/yyyy): 10-19-00

4. Date of this report (m/d/yyyy): 12-24-00

5. Describe event or problem
 pt adm. H/O to ICU for GI bleed - coffee ground emesis & 10 days - EGD showed NSAID gastropathy

6. Relevant tests/laboratory data, including dates

Date	#/H
7-18	5.3 / 15.4
11-18	8.2 / 23.9
12-11	8.8 / 25.3
10-26	9.5 / 27.7

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 HTN, CVA, Arthritis, hyperlipidemia
 CTG 134598

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) (m/d/yyyy)
#1 Naprosyn	bid	#1
#2 NAPROSYN		#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 arthritis	#1 <input 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 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

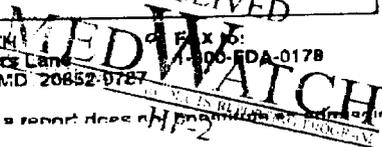
1. Brand name	4. Operator of device
2. Type of device	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
3. Manufacturer name & address	5. Expiration date (m/d/yyyy)
-	DEC 26 2000
RECEIVED	
6. Model #	7. If implanted, give date (m/d/yyyy)
DEC 26 2000	
8. Catalog #	8. If explanted, give date (m/d/yyyy)
MEDWATCH CTU	
9. Serial #	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/yyyy)
10. Lot #	10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone # Pharm.D. Pharmacy Department, Hospitals St. Tel. _____	2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	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 type="checkbox"/>			



Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-0787





For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting.

APPROVED BY FDA ON 03/06/98

Mfr report #	251366
UF/Dist. report #	
FDA Use only	

1 of 2

A. Patient information

1. Patient Identifier	2. Age at time of event: or 51 YEARS Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 205 lbs or 93 kgs
-----------------------	---	---	--------------------------------------

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or	<input type="checkbox"/> Product problem (e.g., defects/maifunctions)
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 prolonge	<input checked="" type="checkbox"/> permanent impairment/damage
	<input type="checkbox"/> other:
3. Date of event DEC / / 1990 E	4. Date of this report JAN / 02 / 2001

5. Describe event or problem

THIS SPONTANEOUS CASE, REPORTED BY A CONSUMER, CONCERNS A 51 YEAR OLD MALE PATIENT WHO WAS HOSPITALISED WITH CORONARY ARTERY DISEASE, A DUODENAL ULCER AND HAD EROSIIVE GASTRITIS FOLLOWING THE USE OF NAPROSYN (NAPROXEN) FOR SHOULDER PAIN.

THE PATIENT HAS A MEDICAL HISTORY OF DIABETES FOR WHICH HE WAS TAKING DIABINESE (CHLORPROPAMIDE) CONCOMITANTLY. THE PATIENT DOES NOT DRINK ALCOHOL BUT HAS A HISTORY OF SMOKING (STOPPED 1980) AND HAS NO DRUG ALLERGIES.

OCT 1990: THE PATIENT TOOK APPROX. 4-5 TABLETS OF PO NAPROSYN FOR 1 WEEK ONLY (DOSING AND REGIMEN WERE UNSPECIFIED). THE PHYSICIAN INITIALLY DIAGNOSED THE PATIENT'S SHOULDER PAIN AS ARTHRITIS. THE PATIENT DISCONTINUED NAPROSYN AFTER 1 WEEK AS HE FELT THAT IT DID NOT HELP HIM THAT MUCH.

DEC 1990: THE SHOULDER PAIN CONTINUED AND THE PATIENT WAS DIAGNOSED WITH CORONARY ARTERY DISEASE.

8 JAN 1991: THE PATIENT UNDERWENT CORONARY

CONTINUED

6. Relevant tests/laboratory data, including dates

UNK

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

Medical History Terms
DIABETES
SMOKER

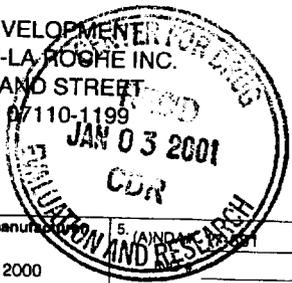
Medical History Text
THE PATIENT DOES NOT DRINK ALCOHOL AND HAS NO DRUG ALLERGIES.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)	
#1 NAPROSYN (NAPROXEN)	
#2 NA	
2. Dose, frequency & route	3. Therapy dates (if unk. give duration from to or best estimate)
#1 ORAL	#1 15-OCT-1990 E / 15-OCT-1990 E
#2 NA	#2 NA
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 SHOULDER PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" 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 UNK	#1 UNK
#2 NA	#2 NA
9. NDC # for product problems only (if known)	8. Event reappeared after reintroduction
#1 NA #2 NA	#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)	
DIABINESE UNK (CHLORPROPAMIDE)	

G. All manufacturers

1. Contact Office-name/address	2. Phone Number
GLOBAL DEVELOPMENT ENTERPRISES HOFFMANN-LA ROCHE INC. 340 KINGSLAND STREET NUTLEY, NJ 07110-1199	(973) 562-3523
4. Date received by manufacturer	5. (AND) Date received by user
DEC / 19 / 2000	
6. If IND, protocol #	7. Type of report (check all that apply)
NA	<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
CORONARY ARTERY DISEASE +++ DUODENAL ULCER -GASTRO INTESTINAL BLEEDING -STOMACH PAIN -SKIN DISCOLOURATION GASTRITIS EROSIIVE	251366
+++ adverse event that generated submission - comanifestation	
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:	



E. Initial reporter

1. Name, address & phone #	2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
[Redacted] ST. [Redacted] UNITED STATES OF AMERICA	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	N/A	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk.

JAN 04 2001
CONTINUED



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

E-Indicates estimated date or dose, P-Indicates partial date

JAN 03 2001

Mfr report # 251366



B.5. Describe event or problem - continued

ARTERY BYPASS GRAFT SURGERY (DOUBLE BYPASS).

18 JAN 1991 (EST.): THE PATIENT WAS RELEASED FROM HOSPITAL IN A GOOD CONDITION.

DATE UNKNOWN: IN THE YEARS FOLLOWING THE HOSPITALISATION FOR BYPASS SURGERY, THE PATIENT WAS DIAGNOSED WITH EROSIIVE GASTRITIS AND HE ALSO HAD SOME BLOOD IN HIS STOOL.

28 JAN 2000: THE PATIENT DEVELOPED STOMACH PAIN AND TURNED WHITE. HE WAS TAKEN TO HOSPITAL WHERE HE WAS IMMEDIATELY ADMITTED AND DIAGNOSED WITH A DUODENAL ULCER. THE REPORTER, WHO WAS THE PATIENT'S WIFE, STATED THAT THE ULCER COVERED 75% OF THE DUODENUM AND THAT THE PATIENT LOST 75% OF HIS BLOOD AND REQUIRED A TRANSFUSION OF 7 UNITS OF BLOOD.

4 FEB 2000: THE PATIENT WAS DISCHARGED.

AT THE TIME OF THE REPORT, THE PATIENT'S CARDIAC STATUS WAS STABLE SINCE SURGERY IN 1991. HE WAS CURRENTLY TAKING CARDURA (DOXAZOCIN) AND PRILOSEC (OMEPRAZOLE) AND WAS ASYMPTOMATIC. THE REPORTER ALSO STATED THAT THE PATIENT WAS INVOLVED IN A WORKER'S COMPENSATION CASE AGAINST HIS FORMER EMPLOYER. SHE ALSO STATED THAT THE PATIENT WAS UNDER PROLONGED AND SEVERE STRESS WHILE WORKING WITH HIS COMPANY WHICH THEY FELT CAUSED HIM TO DEVELOP HEART DISEASE AND A DUODENAL ULCER.

THE COMPANY CONSIDERED THE CORONARY ARTERY DISEASE TO REQUIRE INTERVENTION AND THE EROSIIVE GASTRITIS TO BE MEDICALLY SIGNIFICANT. NO FURTHER INFORMATION WAS PROVIDED.

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: [REDACTED]

DSS

JAN 04 2001

JAN 03 2001