

Individual Safety Report



3771397-0-00-01

VOLUNTARY reporting
 health professionals of adverse
 events and product problems

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
 See OMB statement on reverse

FDA Use Only

Triage unit
 sequence #

148447

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information			
1. Patient identifier 080601	2. Age at time of event: 77 Years or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 87.8 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"/> life-threatening <input checked="" type="checkbox"/> hospitalized or treatment prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other			
3. Date of event 07/17/2001	4. Date of this report 08/06/2001		
5. Describe event or problem GI blood loss and anemia found prior to having surgery for peripheral vascular disease.			
6. Relevant tests/laboratory data, including dates Hgb = 9.7			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) ASCVD, Hyperlipidemia, Dyspepsia, Macular Degeneration of Right eye, Bilateral Cataract Disease, S/P Aortobifemoral Bypass Surgery, Status Post Bilateral Femoral-Popliteal Bypass Surgery			

DSS

AUG 07 2001

RECEIVED
 AUG 07 2001
 MEDWATCH CTU

MEDWATCH
 AUG 07 2001



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

FDA Form 3500

Submission of a report constitutes an admission that medical personnel or the product caused or contributed to the event.

C. Suspect medication(s)			
1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)			
#1 Plavix / 75 mg			
#2 Aspirin / 80 mg			
2. Dose/Frequency/Route used		3. Therapy dates (if unknown, give duration; From To (or best estimate))	
#1 75 mg / QD / Oral		#1 04/05/2001 - 07/17/2001	
#2 80 mg / QD / Oral		#2 04/05/2001 - 07/17/2001	
4. Diagnosis for use (separate indications with commas)		5. Event abated after use stopped or dose reduced	
#1 Occluded Femoral Popliteal Bypass Graft		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1	#1		
#2	#2		
9. NDC # (for product problems only)			
10. Concomitant medical products and therapy dates (exclude treatment of event) Lipator 10mg HS, Cimetidine 400mg HS, Multivitamins QD, Sennakot prn			
D. Suspect medical device			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
6. model #		5. Expiration date (mm/dd/yyyy)	
catalog #		7. If implanted, give date (mm/dd/yyyy)	
serial #		8. If explanted, give date (mm/dd/yyyy)	
lot #			
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 (exclude treatment of event)			
E. Reporter (see confidentiality section on back)			
1. Name		phone #	
PharmD			
Health System Pharmacy		Drive	
United States			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Pharmacist	
4. Also reported to <input checked="" 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"/>			

CTU 148447

Individual Safety Report



VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **148571**

Internet Submission Page 1

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 173 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 01/31/2001 (mm/dd/yyyy)

4. Date of this report 08/08/2001 (mm/dd/yyyy)

5. Describe event or problem

[redacted] presented to the ER with black stool on day prior to admission and day of admission. The patient also complained of being lightheaded for the previous week. The patient was diagnosed and admitted as having a GI bleed. A closer look at her medication history revealed the initiation of Fosamax four weeks previously. An EGD was performed revealing a single diverticula in the midesophagus and a large paraesophageal hernia. Fosamax was discontinued from her medication profile and Prevacid 30mg QAM was initiated. The patient slowly improved and the GI bleed resolved. Discharge medications included all her previous medications in addition to Prevacid 30mg QAM.

6. Relevant tests/laboratory data, including dates

1/31: Hgb/Hct= 13.2/38.4
2/01: Hgb/Hct= 10.1/29.3
All other labs -e.g. K, Cl, Mg- WNL

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

[redacted] has a PMH significant for hypertension, hyperlipidemia, osteoporosis, and myasthenia gravis. She also has peptic ulcer disease with a past history significant for H. pylori positive serology.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Fosamax / 70mg / Merck #2 ASA/Prednisone / 81mg/10mg / Generic	2. Dose/Frequency/Route used #1 70mg / Weekly / Oral #2 81mg / QD / Oral	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 01/01/2001 - 01/31/2001 #2 -
4. Diagnosis for use (separate indications with commas) #1 Osteoporosis #2 Hyperlipidemia/Myasthenia gravis	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	6. Lot # (if known) 7. Exp. date (if known) #1 #1 #2 #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 (exclude treatment of event) Mestinon 40mg TID Imuran 50mg TID Zocor 40mg QD Diovan 80mg QD Occuvite vitamins

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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AUG 08 2001

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

5. Expiration date (mm/dd/yyyy)

6. model # MEDWATCH CTU

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

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

9. Device available for evaluation? yes no returned to manufacturer on (mm/dd/yyyy)

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

AUG 09 2001

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]

[redacted] Pharm.D.
[redacted] Hospital
[redacted] Street

United States

2. Health professional? yes no

3. Occupation Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

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



Mail to: MEDWATCH AUG 03 2001
5600 Fishers Lane
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.

MEDWATCH
CTU148571
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DuPont Pharmaceuticals Company

Domain Facsimile
Mfr report #
2000COU1043
JP-001 report #

Approved by FDA on 3/12/04

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 3

FDA Use Only

A. Patient information

1. Patient identifier [redacted] 2. Age at time of event: 73 yrs
3. Sex: female male
4. Weight: 212 lbs or kgs

Date of birth: NI

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): 03/??/2000 4. Date of this report (month/year): 06/22/2001

5. Describe event or problem

Initial Notification (24-Aug-00)

A 73-year-old female had OCCULT BLOOD IN HER STOOL on 23-Mar-00 and was hospitalized for an endoscopy on 9-Jun-00. The start date and indication for Coumadin were unspecified. She began taking Cordarone (amiodarone) in 1994 for atrial fibrillation and Celebrex 100 mg BID in Mar-00 for OSTEOARTHRITIS.

On 23-Mar-00, while taking Coumadin, Celebrex, and aspirin, the patient tested positive for occult blood in her stool (home positive stool). On 3-May-00 during a routine ECG, she was found to have a PROLONGED QTc INTERVAL OF >500 and SINUS BRADYCARDIA. The patient also had *

6. Relevant tests/laboratory data (including dates)

23-MAR-2000 Occult Blood Positive x 3
03-MAY-2000 Electrolytes, Liver Function Test, & Thyroid Panel Results: Within normal limits
03-MAY-2000 Electrocardiogram Prolongation of QTc (517 msec) *

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

Allergies: penicillin
Hypertension
Rate-dependent right bundle branch block
Right total knee arthroplasty
Coronary artery disease
Peptic ulcer disease (surgery) - *

C. Suspect medication(s)

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

#1 COUMADIN (Crystalline Warfarin Sodium)
#2 CELEBREX (CELECOXIB)

2. Dose, frequency & route used

#1 UNKN UNKN PO #2 100 MG BID PO

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

#1 NI, unknown #2 ??-MAR-2000 to 03-MAY-2000

4. Diagnosis for use (indication)

#1 UNKN CAUSE MORB/MORT NEC #2 OSTEOARTHROS NOS - UNSPEC

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply #2 yes no doesn't apply

6. Event reappeared after reintroduction

#1 yes no doesn't apply #2 yes no doesn't apply

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

#1 NI #2 NI

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

Name: NI (NETOPROLOL) Dates: NI to NI
Name: NI (ENALAPRIL) Dates: NI to NI
Name: NI (AMLODIPINE) Dates: NI to NI
Name: NI (HYDROCHLOROTHIAZIDE) Dates: NI to NI *

G. All manufacturers

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

DuPont Pharmaceuticals Company
Chestnut Run Plaza, HR1132
P.O. Box 80723
Wilmington DE 19880-0723 USA

2. Phone number (302) 892-0694

3. Report source (check all that apply)

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

4. Date received by manufacturer (month/year): 08/24/2000

5. (A)NDA # 9-218
IND #
PLA #
pre-1938 yes no
OTC product yes no

6. If IND, protocol #

7. Type of report (check all that apply)

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

8. Adverse event term(s)

MELAENA, ARTHRITIS, QT INCREASED, BRADYCARDIA, FIBRILLATION ATRIAL, FATIGUE

9. Mfr. report number
2000COU1043

E. Initial reporter

1. Name, address & phone #
[redacted] College of Pharmacy
[redacted] Street, Room [redacted]
[redacted] USA *

2. Health professional? yes no

3. Occupation
Pharmacist

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



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

Domain Facsimile of FDA Form 3500A

AUG 02 2001

Volume I Page 182



DuPont Pharmaceuticals Company

Domain Facsimile
Mfr report # 2000COU1043
JF/Dist report #
Approved by FDA nr. 35294
FDA Use Only

Page 2 of 3

MED WATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

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

B. Adverse event or product problem

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

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

3. Date of event (month/year): _____
4. Date of this report (month/year): _____

5. Describe event or problem: _____

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #3 NI (ASPIRIN - UNSPECIFIED)
 #4 CORDARONE (AMIODARONE HYDROCHLORIDE)

2. Dose, frequency & route used
 #3 UNK UNK UNK
 #4 100 MG QD PO

3. Therapy dates (if unknown, give duration; month or best estimate)
 #3 NI, unknown
 #4 ??-??-1994, continuing

4. Diagnosis for use (indication)
 #3 UNKN CAUSE MORB/MORT NEC
 #4 ATRIAL FIBRILLATION

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

6. Lot # (if known)
 #3 NI
 #4 NI

7. Exp. date (if known)
 #3 NI
 #4 NI

8. Event reappeared after reintroduction
 #3 yes no doesn't apply
 #4 yes no doesn't apply

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

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

G. All manufacturers

1. Contact office - name/address (if mailing site for devices)
2. Phone number

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

4. Date received by manufacturer (month/year): _____

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

6. Adverse event term(s): _____

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

8. Mfr. report number

5. Relevant tests/laboratory data, including dates: _____

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

E. Initial reporter

1. Name, address & phone #

2. Health professional? yes no

3. Occupation

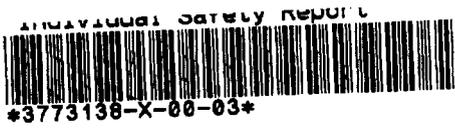
4. Initial reporter also sent report to FDA yes no unk

FDA

Domain Facsimile of
FDA Form 3500A

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

AUG 02 2001



DuPont Pharmaceuticals Company

MED WATCH	A.1. Patient identifier	G.3. Mfr. report number	Page 3 of 3
	[REDACTED]	2000COU1043	

B.5. Describe event or problem

[continuation:] INCREASED FATIGUE and decreased exercise tolerance. On 3-May-00, Celebrex and Cordarone were discontinued due to the prolonged QTc interval. The patient refused hospitalization and was treated with Coumadin as an outpatient. On 5-May-00, an ECG indicated that the patient was in ATRIAL FIBRILLATION and Cordarone was resumed. On 10-May-00, a repeat ECG revealed the QTc interval to be back to normal at 418 msec. On 9-Jun-00, the patient was hospitalized for an endoscopy to evaluate the heme positive stools. As of 13-Jun-00, the patient was still hospitalized. The reporter suspected that the prolonged QTc interval was due to a drug interaction between Celebrex and amiodarone and that the heme positive stools could be attributed to Coumadin and possibly Celebrex. The patient's past medical history is significant for hypertension, right bundle branch block, right total knee arthroplasty, peptic ulcer disease with surgery, and coronary artery disease.

The information was provided in a Form FDA 3500A forwarded by Searle Pharmaceuticals (manufacturer control number 000614-SK188).

B.6. Relevant tests/laboratory data including dates

[continuation:] 05-MAY-2000 Electrocardiogram Atrial Fibrillation
10-MAY-2000 Electrocardiogram Baseline QTc (418)
09-JUN-2000 Endoscopy Result not provided

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

[continuation:] unspecified date)
Current tobacco and alcohol use denied
Race: BLACK

C.19. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: NI (ISOSORBIDE DINITRATE) Dates: NI to NI

E.1. Name, address & phone #

[continuation:] Phone: [REDACTED]

AUG 02 2001



ck Human Health Division

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

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

NO ATTACHMENT

50338227

Mfr report #	WAES 01080056
UF/Dist report #	
FDA Use Only	

RECEIVED

A. Patient information			
1. Patient identifier [REDACTED]	2. Age at time of event: or 53 years Date of Birth:	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight Unk
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 (mo/day/yr) 07/15/01	4. Date of this report (mo/day/yr) 08/07/01		
5. Describe event or problem			
<p>Information has been received from a 53 year old female patient who was placed on therapy with rofecoxib, 25 mg tablet, once a day (duration and indication not reported). Concomitant therapy included aspirin (duration, dose, and indication not reported), montelukast sodium (MSD), fluticasone propionate (+) salmeterol xinafoate (ADVAIR DISKUS), ranitidine HCl, isosorbide mononitrate, prednisone (DELTASONE), albuterol, lansoprazole (PREVACID), amlodipine besylate (NORVASC), amitriptyline hydrochloride, atenolol, ibuprofen, estrogens, conjugated (PREMARIN) and nitroglycerin (NITROLINGUAL). On approximately 15-JUL-2001 the patient was hospitalized for gastrointestinal bleeding. The patient stated that she developed gastrointestinal bleeding from taking rofecoxib and aspirin. At the time of this report the patient had recovered.</p> <p>Additional information has been requested.</p>			
6. Relevant tests/laboratory data, including dates			
Unknown			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
Unknown			

C. Suspect medication(s)			
1. Name (give labeled strength & formulation, if known)			
# 1 TAB VIOXX 25 mg			
# 2 aspirin Unk			
2. Dose, frequency & route used		3. Therapy dates (from/to) (if unknown, give duration)	
# 1 25 mg/DAILY/PO		# 1 Unk - Unk	
# 2 Unk/Unk/Unk		# 2 Unk - Unk	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced.	
# 1 Unknown		yes no N/A unk	
# 2 Unknown		# 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	
6. Lot # (if known)		7. Exp date (if known)	
# 1		# 1	
# 2		# 2	
		8. Event reappeared after reintroduction.	
		yes no N/A unk	
		# 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	
		# 2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	
9. NDC # - for product problems only (if known)			
Unknown			
10. Concomitant medical products and therapy dates (excluded treatment of event)			
ADVAIR DISKUS		Unk -Unk	
DELTASONE		Unk -Unk	

(Continued on Additional Page)

G. All manufacturers	
1. Contact office - name/address	2. Phone Number
Merck Human Health Division	(484)344-2416
Merck & Co., Inc.	
P.O. Box 4	
West Point, PA 19486-0004	
ATTN: Worldwide Product Safety	
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) 07/30/01	5. (A)NDA # 21042
	IND # _____
	PLA # _____
6. If IND, protocol #	pre-1938 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes
7. Type of report	9. Mfr. report number:
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	WAES 01080056
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input checked="" type="checkbox"/> initial <input type="checkbox"/> Follow-up# _____	
8. Adverse event term(s) GASTROINTESTINAL BLEEDING	

E. Initial reporter		
1. Name, address & phone # Confidential Report United States		
<p>DSS</p> <p>AUG 10 2001</p> <p>AUG 09 2001</p>		
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

FDA

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



3774272-0-00-02

10. Concurrent medical products and therapy dates (exclude treatment of event)		
NITROLINGUAL	Unk	- Unk
NORVASC	Unk	- Unk
PREMARIN	Unk	- Unk
PREVACID	Unk	- Unk
SINGULAIR	Unk	- Unk
albuterol	Unk	- Unk
amitriptyline hydrochloride	Unk	- Unk
atenolol	Unk	- Unk
ibuprofen	Unk	- Unk
isosorbide mononitrate	Unk	- Unk
ranitidine hydrochloride	Unk	- Unk

DSS

AUG 10 2001

AUG 09 2001



30 July 2001

Relsys International, Inc
FDA Facsimile Approval: 30-JUN-1999
Mr. report # 2001050358US
UF/Dist. report #
FDA Use Only

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Manufacturers for
MANDATORY reporting
Pharmacia & Upjohn, Inc.

Periodic Page 431 - 1

A. Patient information

1. Patient identifier [redacted] in confidence	2. Age at time of event: 54 years or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 155.0 lbs or 70.3 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"/> 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: 08/--/2000

4. Date of this report: 07/19/2001

5. Describe event or problem

Abdominal pain[Abdominal pain NOS]
Gastritis[Gastritis NOS]
Spasms[Muscle spasms]
Felt weak[Weakness]
Felt sweaty[Sweating increased]
Ulcers bleeding[Gastric ulcer haemorrhage]
No relief from pain[Drug ineffective]

Case Description:
Spontaneous Report

On 27MAR2001, a consumer called to report adverse events from CELEBREX. This 54 year old female consumer with a history of ulcers, started CELEBREX (celecoxib) 100 mg daily in 1999 for chronic pain after multiple traumas. In AUG2000, she reports that she had no relief from her pain and her dose was increased to 200 mg with breakfast and 200 mg with dinner. In AUG2000, an upper gastrointestinal series continued in additional info section...

6. Relevant tests/laboratory data, including dates

AUG2000: Upper gastrointestinal series showed gastritis, but no ulcers

19MAR2001: Endoscopy performed and found scattered small ulcerations in the antrum. Assessment; Gastric ulcers, most likely due to aspirin. Plan: Discontinue all aspirin products and maximize antacid

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

#1 11/--/1990 to UNK concurrent condition. (continued)
#2 11/--/1990 to UNK concurrent condition. (continued)
#3 --/--/1996 to UNK medical history. (continued)
#4 concurrent condition. (continued)

C. Suspect medication(s)

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

1. CELEBREX(CELECOXIB) (continued)

2. FIORINAL WITH CODEINE(BUTAL) (continued)

2. Dose, frequency & route used

1. 100 mg, qd, oral

2. UNK, UNK, UNK

3. Therapy dates (if unknown, give duration)

1. --/--/1999 to 08/--/2000

2. --/--/1997 to Ongoing

4. Diagnosis for use (indication)

1. Pain NOS

2. Unknown

5. Event abated after use stopped or dose reduced

1. yes no doesn't apply

2. yes no doesn't apply UNK

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

1. UNK # 1. UNK

2. UNK # 2. UNK

8. Event reappeared after reintroduction

1. yes no doesn't apply

2. yes no doesn't apply UNK

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

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

LANSOPRAZOLE --/--/1999 to ongoing
CARISOPRODOL --/--/1997 to ongoing

G. All Manufacturers

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

Pharmacia
Cheryl Watton, M.D.
Safety Officer
7031-248-GDS
7000 Portage Road
Kalamazoo, MI 49001 UNITED STATES

2. Phone number
(616)833-8777

3. Report source (check all that apply)

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

4. Date received by manufacturer
04/24/2001

5. (A)NDA # 20998
IND #
PLA #
pre-1938 yes
OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day
 10-day periodic
 initial follow-up # 1

8. Adverse event term(s)
Abdominal pain NOS, Gastritis NOS, Muscle spasms, Weakness, Sweating increased, Gastric ulcer haemorrhage, continued in additional info section...

9. Mfr. report number
2001050358US

E. Initial reporter

1. Name & address phone #
Dr. [redacted]
[redacted] Street Suite [redacted]
[redacted] UNITED STATES

2. Health professional? yes no

3. Occupation physician

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.

500A - Facsimile

JUL 31 2001

30 July 2001

Individual Safety Report



ME

3776544-2-00-02

(continued)

report does not constitute medical personnel, user, manufacturer or product attributed to the event.

Pharmacia & Upjohn, Inc.
 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Public Health Service - Food and Drug Administration

Mfr report # 2001050358US
 UF/Dial. report #

FDA Use Only

Periodic Page 431 - 2

Additional Information

B5. EVENT DESCRIPTION (cont.)

showed she did have gastritis but no ulcers. The increased dose of CELEBREX did help relieve her chronic pain. In NOV2000, she began to experience abdominal pain. In DEC2000, the pain continued and she decreased the CELEBREX to 100 mg daily. In FEB2001, the abdominal pain increased with spasms of pain and she was started on Levsin. On 09MAR2001, she had an increase in the abdominal pain and felt weak and sweaty. CELEBREX was discontinued due to the abdominal pain. On 12MAR2001, an endoscopy revealed several small ulcers that were bleeding. As of 27MAR2001, it is not clear if her abdominal pain is better or worse, but her chronic pain has worsened.

Additional information was received on 24APR2001. The consumer's surgeon reported that the gastric ulcers noted on 19MAR2001 (correct date of endoscopy) were most likely due to aspirin in Fiorinal. A copy of the consumer's endoscopy report was also sent and the assessment stated that the gastric ulcers were most likely due to aspirin. In the report, the surgeon stated that they would discontinue all aspirin products and maximize antacid effect with an over-the-counter H2 receptor antagonist at bedtime.

Additional information was received on 29MAY2001. The consumer's surgeon reported that she was not aware of any adverse reaction to CELEBREX. She stated the consumer had small superficial non-bleeding ulcers which were secondary to the aspirin in Fiorinal.

B6. RELEVANT TESTS (cont.)

effect with over-the -counter H2 receptor antagonist at bedtime.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	11/--/1990	concurrent condition Pain NOS	Chronic pain caused by motor vehicle accident
2	11/--/1990	concurrent condition Migraine NOS	Caused by motor vehicle accident
3	--/--/1996	medical history Gastric ulcer	
4		concurrent condition Irritable bowel syndrome	

C1. Name (cont.)

Suspect Medication #1: CELEBREX(CELECOXIB) capsule
Suspect Medication #2: FIORINAL WITH CODEINE(BUTALBITAL, PHENACETIN)

G8. ADVERSE EVENT TERMS (cont.)

Drug ineffective

Block C - Additional Dosage Regimens

Suspect Product	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)	6. Lot # (if known)	7. Exp. date (if known)
#1 CELEBREX Regimen # 2	200 mg, bid, oral	08/--/2000 to 12/--/2000	UNK	UNK
#1 CELEBREX Regimen # 3	100 mg, qd, oral	12/--/2000 to 03/09/2001	UNK	UNK

JUL 31 2001

Individual Safety Report



3778332-X-00-01

Voluntary reporting by health professionals of adverse events and product problems

FDA Use Only

Triage unit sequence #

149223

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page: 1

42-209

Age of patient at time of event: 77

Sex: Female Male

Date of Onset: 03-00

Date of this report: 06-07-01

B. Adverse event or product problem

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

Outcomes attributed to adverse event

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other: Resolved

Date of event: 03-00

Date of this report: 06-07-01

5. Describe event or problem

GI bleed

Relevant tests/laboratory data, including drug levels

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ASPICIN (Aspirin) 325mg

2. Diagnosis for use of medication

6. Lot # (if known) #1

7. Exp. date (if known) #1

9. NDC # (for product problems only)

Brand name

Type of device

Manufacturer name

Model #

Category #

Serial #

Lot #

Other #

8. Device available for evaluation? yes no DSS

9. Concomitant medical products

10. Other

E. Reporter (see confidentiality section on back)

1. Name: [Redacted] Ph.D., FASCP, R.Ph. Director of Pharmacy Services
Memorial Hospital

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.

RECEIVED
AUG 16 2001
MEDWATCH CTU

DSS
AUG 16 2001

CTV149223



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

Individual Safety Report



3778382-3-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

FDA Use Only

Triage unit
sequence # **149261**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

1. Patient information
Patient identifier: **S3-703**
Age at time of event: **76**
Sex: female male
Date of birth: _____
Weight: _____ lbs / _____ kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply)
 death disability
 hospitalization congenital anomaly
 permanent impairment/damage
 other **RESOLVED**

3. Date of event: **01-00**
4. Date of this report: **06-05-01**

5. Describe event or problem

**Hematemesis,
thrombocytopenia**

6. Relevant tests/laboratory data, including dates:

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

C. Suspect medication(s)

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

#1 **Coumadin (ASA)**

2. Lot # (if known) #1 _____
3. Exp. date (if known) #1 _____

4. Diagnosis for use medication:
#1 _____

5. NDC # (for product problems only)
#1 _____

6. Brand name
7. Type of device
8. Manufacturer name & address

9. Model #
10. Catalog #
11. Serial #
12. Lot #
13. Other #

14. Device available for evaluation?
 yes no

15. Concomitant medical products used (e.g., other drugs, biologics, etc.):

**RECEIVED
AUG 16 2001
MEDWATCH CTU
DSS
AUG 16 2001**

E. Reporter (see confidentiality section on back)

1. Name: **[Redacted]**
Title: **Director of Pharmacy Services**
Address: **Memorial Hospital**

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.

CTV149261

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

Individual Safety Report



3778431-2-00-01

Voluntary reporting
of health professionals of adverse
events and product problems

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

FDA Use Only

Triage unit
sequence # 149140

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of CDAR

A. Patient information

1. Patient identifier 38-371
2. Age at time of event: 52
3. Sex: female male
4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/ malfunctions)
2. Outcomes attributed to adverse event (check all that apply):
 death (m/d/day/yr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: Resolved
3. Date of event (m/d/day/yr): 07-00
4. Date of this report (m/d/day/yr): 06-07-01

5. Describe event or problem
melanotic stools

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.)
CTV149140

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Aspirin 4 Adult
2. Dose, frequency & route used
3. Therapy dates (if unknown, give duration)
4. Diagnosis for use (indication)
5. Event abated after use stopped or dose reduced
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)

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 # MEDWATCH CTU
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)
DSS
AUG 16 2001

E. Reporter (see confidentiality section on back)

1. Ph.D., FASCP, M.P.H.
Director of Pharmacy Services
Avenue
P.O. Box
Memorial Hospital
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



3778122-5-00-01

Voluntary reporting by professionals of adverse events and product problems

FDA Use Only Triage unit sequence # 149047

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

A. Patient information

1. Patient identifier: 238-021; 2. Age at time of event: 50; 3. Sex: [] 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, [] hospitalization, [] disability, [] congenital anomaly, [] required intervention to prevent permanent impairment/damage, [X] other: Resolved; 3. Date of event: 10-00; 4. Date of this report: 06-10-01

5. Describe event or problem

Gastritis, Duodenitis with prominent erosions

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 Aspirin/Celebrex; 2. Dose, frequency & route used; 3. Therapy dates; 4. Diagnosis for use; 5. Event abated after use stopped or dose reduced; 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

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. Reporter name: Ph.D., FASCP, R.Ph. Director of Pharmacy Services; 2. Health professional? [X] yes; 3. Occupation: Pharmacist; 4. Also reported to: [X] 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



Approved by FDA 11/10/94

Mfr report #	2001-BP-02368
UF/Dst report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [REDACTED] in confidence	2. Age at time of event: 70 YEARS or Date of birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or UNK 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 checked="" type="checkbox"/> death 07/03/2001 (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: UNK (mo/day/yr)	4. Date of this report: 08/17/2001 (mo/day/yr)

5. Describe event or problem

International ID: 01-BP-02368

A physician reported to a BI sales representative that he had a 70 year old female patient who began using Mobic Tablets 7.5 mg, one tablet daily for osteoarthritis eight days ago. The patient is a heavy smoker and is also taking Evista (raloxifene), Ativan (lorazepam), nifedipine and Excedrin (acetaminophen, aspirin and caffeine) (2 per day). On the eighth day of Mobic therapy, the patient was rushed to the hospital due to gastric hemorrhage and treated by another physician. Excedrin was considered to be an alternate suspect drug. The patient died (date not specified). On 10Jul01 the physician was contacted but no new information was obtained. Additional information received on 16Jul01: The patient had a medical history which included hemorrhoids, tonsillectomy and adenoidectomy (as a child), and a history of a lumpectomy. She had an allergy to Penicillin. Additional concomitant medications were reported: Nifedipine and Keftabs. It is noted that on 02Jul01, MOBIC had a positive effect, although the patient was still with some back pain. She was encouraged to take 2, 7.5 mg of MOBIC. On 03Jul01, she was admitted to the CCU after sustaining a massive upper GI bleed with hypotension and cardiovascular collapse. The patient was

CONTINUED

6. Relevant tests/laboratory data, including dates

NONE

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

HEAVY SMOKER ONSET UNK
HEMORRHOIDS ONSET X 2
TONSILS AND ADENOIDS REMOVED ONSET AS A CHILD
RIGHT LUMPECTOMY ONSET 4-5 YEARS AGO
PENICILLIN ALLERGY ONSET UNK
AORTIC ANEURYSM GRAFT ONSET UNK

8. Adverse event term(s)

GI HAEMORRHAGE

9. Mfr. report number

2001-BP-02368

FDA 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 MOBIC (MELOXICAM) TABLETS/7.5 MG	
#2 EXCEDRIN	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from:to (or best estimate)
#1 7.5 MG/1 TABLET DAILY/PO	#1 UNK-UNK/8 DAYS
#2 2 RT/NR	#2 UNK-UNK/NR
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 OSTEOARTHRITIS	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 NOT REPORTED	#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 NR	#1 UNK
#2 UNK	#2 UNK
8. Event reappeared after rein-reduction	
#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)	
EVISTA (RALOXIFENE) UNK-UNK/MONTHS ATIVAN (LORAZEPAM) UNK-UNK/MONTHS-PRN NIFEDIPINE XL UNK-UNK/MONTHS KEFTABS UNK-UNK/10 DAYS	

G. All manufacturers

1. Contact office - name/address (& mfring. site for devices)	2. Phone number
Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877-0368	(203) 798-4361
4. Date received by manufacturer (mo/day/yr)	5. (A)NDA #
08/08/2001	20-938
6. If IND, protocol #	IND #
	PLA #
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1	
8. Adverse event term(s)	
GI HAEMORRHAGE	
9. Mfr. report number	
2001-BP-02368	

E. Initial reporter

1. Name, address and phone #			
[REDACTED] M.D.			
UNITED STATES OF AMERICA [REDACTED]			
[REDACTED]			
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	

AUG 23 2001



Approved by FDA 11/10/94

Mfr report #	2001-EP-02368
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

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

B. Adverse event or product problem

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

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

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

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

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

5. Describe event or problem

put on life support and given 6 units of packed cells, 4 units of fresh frozen plasma, and crystalloid. She died on 03Jul01 at 11:30 pm. Follow-up information received on 08Aug01: The patient had a past history of aortic aneurysm graft. She presented to the hospital with progressive fatigue and hypotension. Initial consideration was given for primary cardiac versus sepsis syndrome. She experienced one episode of heart block (type II) and was then treated with heparin for chest pain and EKG/rhythm changes with the resulting GI bleed. The patient was then intubated, aggressive resuscitation efforts performed, including "massive" blood infusion. The physician suspects that the patient developed an aorto-esophageal fistula with a resulting hemorrhage, unrelated to her NSAID use. Information received reports that it is unknown if an autopsy has been performed.

6. Relevant tests/laboratory data, including dates

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

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 estimate)

4. Diagnosis for use (indication)

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

6. Lot # (if known)

7. Exp. date (if known)

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

9. NDC # - for product problems only (if known)
 yes no doesn't apply

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

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: _____

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

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

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 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 and phone #

155
AUG 24 2001

2. Health professional?
 yes no

3. Occupation

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

FDA 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.

AUG 23 2001



Kos Pharmaceuticals, Inc.

Domain Facsimile Approved by FDA on 5/22/94

Mfr report # 10412

JFDA report #

FDA Use Only

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 5

A. Patient information

1. Patient identifier [redacted] in confidence

2. Age at time of event: 62 yrs
or Date of birth: [redacted]

3. Sex female male

4. Weight 150 lbs or [redacted] kgs

B. Adverse event or product problem

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

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

death (m/d/yyyy) life-threatening hospitalization - initial or prolonged

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

3. Date of event (m/d/yyyy) 05/31/2001

4. Date of this report (m/d/yyyy) 09/04/2001

5. Describe event or problem

This patient with a history of degenerative hip and spine reported being hospitalized for colitis and gastrointestinal bleeding while on 1000 mg Niaspan. The patient reported that she sought medical attention at the hospital for back pain due to her past history. A colonoscopy revealed a very inflamed colon that bled when touched. Aspirin and Coumadin were discontinued and low dose Heparin therapy was initiated. She reported that she was diagnosed with colitis and gastrointestinal bleeding, and admitted. According to the patient, Flagyl was given for her intestinal bleeding; Vicodin and Oxycodan were given for back and hip pain. She noted that she did not require a blood transfusion while hospitalized and was discharged home after ten days. She *

6. Relevant tests/laboratory data, including dates

09 May 01

WBC = 12.0 M/mm3 normal range: (4.5-11.0)

RBC = 3.67 X 10⁶ normal range: (4.25-5.49)

Hemoglobin = 11.9 G/DL normal range: (12.0-15.7)

Hematocrit = 34.5% normal range: *

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

Myocardial infarction 1991; Quadruple coronary artery by-pass 1991; Mitral valve replacement on two occasions, one of which was in 1991; Right shoulder pain post motor vehicular accident 20 years ago; Degenerative hip and spine; Hypertension; *

C. Suspect medication(s)

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

#1 NIASPAN

#2 NIASPAN

2. Dose, frequency & route used

#1 500 MG QHS PO

#2 1000 MG QHS PO

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

#1 *

#2 16-MAY-2001, unknown

4. Diagnosis for use (indication)

#1 ELEVATED TRIGLYCERIDES

#2 ELEVATED TRIGLYCERIDES

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 UNK

#2 UNK

7. Exp. date (if known)

#1 Unknown

#2 ??-NOV-2003

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)

Name: LIPITOR Dates: UNK, continuing Duration: a few years

Name: PREMARIN Dates: UNK, continuing Duration: a few *

G. All manufacturers

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

Kos Pharmaceuticals, Inc.
14875 NW 77th Ave.
Miami Lakes, FL 33014

2. Phone number (305) 512-7000

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/d/yyyy) 08/21/2001

5. (A)NDA # 20-381

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day

10-day periodic

Initial follow-up # 1

8. Adverse event term(s)

HEMORRHAGIC COLITIS, ANEMIA, BACK PAIN, FLUSHING

SEP 05 2001

9. Mfr. report number 10412

E. Initial reporter

1. Name, address & phone #

Dr. [redacted] STREET [redacted] USA

Phone: [redacted]

DSS

SEP 06 2001

2. Health professional? yes no

3. Occupation PHYSICIAN

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

FDA

Domain Facsimile of FDA Form 3500A

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

Item completed on continuation pages.



3788169-3-00-02

Kos Pharmaceuticals, Inc.

Domain Facsimile

Approved by FDA on 3-22-94

Mfr report #	10412
UF/Dial report #	

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 5

FDA Use Only

A. Patient information			
1. Patient identifier [redacted] in confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input 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 (m/d/yyyy)	<input type="checkbox"/> life-threatening	<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____
3. Date of event (m/d/yyyy)	4. Date of this report (m/d/yyyy)		
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 ENTERIC-COATED ASPIRIN	
#4 COUMADIN	
2. Dose, frequency & route used	
#3 325 MG QHS PO	
#4 2.5 MG UNK PO	
3. Therapy dates (if unknown, give duration) (month or best estimate)	
#3 22-MAY-2001 to 30-MAY-2001	
#4 ??-APR-1994 to 30-MAY-2001	
4. Diagnosis for use (indication)	
#3 PROPHYLAXIS FOR FLUSHING	
#4 HEART VALVE REPLACEMENT	
5. Event abated after use stopped or dose reduced	
#3 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#4 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	
#3 UNK	#3 Unknown
#4 UNK	#4 Unknown
7. Exp. date (if known)	
#3 UNK	#3 Unknown
#4 UNK	#4 Unknown
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 checked="" type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
#3 NA	#4 NA
10. Concomitant medical products and therapy dates (exclude treatment of event)	

G. All manufacturers	
1. Contact office - name/address (& mtng site for devices)	2. Phone number
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:	
4. Date received by manufacturer (m/d/yyyy)	5. (A)NDA # _____
	IND # _____
	PLA # _____
	pre-1938 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes
6. If IND, protocol #	8. Adverse event term(s)
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 # _____	
9. Mfr. report number	

E. Initial reporter		
1. Name, address & phone #		
[redacted]		
[redacted]		
[redacted]		
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

FDA

Domain Facsimile of
FDA Form 3500A

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

SEP 05 2001

DSC
SEP 05



Kos Pharmaceuticals, Inc.

MED WATCH	A.1. Patient Identifier [REDACTED]	G.9. Mfr. report number 10412	Page 3 of 5
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B.5. Describe event or problem

[continuation:] indicated that she felt that the cause of her colitis and gastrointestinal bleeding was due to aspirin and Coumadin.

The patient also reported experiencing flushing while on 500 mg Niaspan. She indicated that the flushing occurred on her feet and was described as itchiness, redness, and warmth. She stated that the flushing felt as if she had a sunburn and relayed that she experienced similar events with increased dosing. The patient stated that while on 500 mg Niaspan she was not instructed to take an aspirin prior to dosing.

Follow-up Information:

Medical records were received on 21 Aug 01, and revealed that the patient, with a history of extensive use of non-steroidal anti-inflammatory drugs, experienced rectal bleeding and hip pain, 2 to 3 days prior to hospitalization. Prior to the rectal bleeding, and hip pain, the patient had experienced 2 or 3 weeks of discomfort in the right lower back, upper gluteal and sacroiliac region, which evolved without a known precipitating factor. Medical records indicated that it was the persistence of the symptoms, and possibly the analgesics taken for the symptoms that gave rise to the gastrointestinal disturbance.

The patient's diagnosis was acute lower gastrointestinal hemorrhage secondary to acute colitis, and anemia due to the gastrointestinal bleed. After 10 days of hospitalization, the patient was discharged home.

SEP 05 2001

DSS
SEP 06 2001



Kos Pharmaceuticals, Inc.

MED WATCH	A.1. Patient Identifier [REDACTED]	G.9. Mfr. report number 10412	Page 4 of 5
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B.6. Relevant tests/laboratory data including dates

[continuation:] (34.9-46.9)

MCH = 32.4 PG normal range: (27.0-31.0)
 Absolute Grans = 7.7 X 10³ normal range: (2.2-4.8)
 Absolute Monos = 1.44 X 10³ normal range: (.11-.59)
 Lymph% = 23% normal range: (24-44)
 ProTime = 25.7 seconds normal range: (11.0-14.0)
 APTT = 54.1 seconds normal range: (25.0-37.0)

30 May 01:

Computer tomography of the lumbar spine = Degenerative disc disease; Degenerative facet arthritis.

31 May 01:

Low hemoglobin

Urea Nitrogen = Increased as a consequence of the bleed.

X-ray = Disc narrowing in multiple areas of the lumbosacral spine. Hips revealed mild joint space narrowing.

Bone scan = Mild osteoarthritic changes at the hips, knees, and spinal area.

Physical examination = Discomfort in the right sacroiliac region(L4-L5); produces discomfort in the right sacroiliac L5-S1 region; hyperreflex ability as the thumb approximates to the forearm; knee flexion generates discomfort at the right L5-S1 region.

June 2001:

Colonoscopy = Colitis which was very inflamed and bled when touched.

01 Jun 01:

Right total hip x-ray = Degenerative changes of the hip.

02 Jun 01:

Pelvic x-ray - Degenerative changes of the pelvis.

06 Jun 01:

Small bowel series = Was performed to rule out a gastrointestinal bleed; result revealed an unremarkable detailed small bowel series.

Hemoccult = positive (date unknown)

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

[continuation:] Elevated cholesterol; Acid reflux; Allergies; Postmenopausal; Restless leg syndrome; Non-insulin dependent diabetes mellitus; Rheumatic fever as a child; Ruptured appendix at nine years old; A second valve (non-specific) replacement 2000; Allergic to penicillin, vancomycin, Biaxin, and adhesive Band-Aids; Smoked for ten years and quit in 1967; Tonsilectomy years ago; Had 5 pregnancies, no miscarriages, the last was associated with considerable disturbance with lower back problems; Hyperreflexability syndrome; Hemarthrosis in one knee; Strong family history of arthritis of the spine, also hip replacements and joint problems in brothers, sisters, and mother; Extensive use of non-steroidal anti-inflammatory drugs

DSS

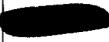
SEP 06 2001

SEP 05 2001



3788169-3-00-05

Kos Pharmaceuticals, Inc.

<p>MED WATCH</p>	<p>A.1. Patient Identifier </p>	<p>G.9. Mfr. report number 10412</p>	<p>Page 5 of 5</p>
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C.3. Therapy dates (if unknown, give duration) (mo/day/yr) (Suspect #1)
UNK to 15-MAY-2001 Duration: 6 months

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

- Name: FUROSEMIDE Dates: ??-APR-1994, continuing Duration: a few years
- Name: PREVACID Dates: UNK, continuing Duration: a few years
- Name: VOIXX Dates: ??-???-2001 to ??-MAY-2001
- Name: ZYRTEC Dates: UNK, continuing Duration: a few months
- Name: PRINIVIL Dates: ??-APR-1991, continuing Duration: a few years
- Name: CLONAZEPAM Dates: UNK, continuing Duration: a few years
- Name: LANOXIN Dates: UNK, continuing Duration: a few years
- Name: POTASSIUM CHLORIDE Dates: UNK, continuing Duration: a few years
- Name: ATENOLOL Dates: UNK, continuing Duration: a few years
- Name: CELEBREX Dates: ??-MAY-2001, continuing Duration: a few weeks
- Name: GLUCOPHAGE Dates: UNK, unknown
- Name: GLUCOTOL Dates: UNK, unknown
- Name: AVANDIA Dates: ??-FEB-2001, unknown
- Name: MUSCLE RELAXER Dates: ??-???-1999, unknown
- Name: KLONOPIN Dates: UNK, unknown

SEP 05 2001

DSS
SEP 06 2001

Individual Safety Report



3790770-8-00-01

VOLUNTARY reporting
 health professionals of adverse
 events and product problems

Form Approved OMB No. 0910-0291 Expires: 04/30/03
 See OMB statement on reverse

FDA Use Only

Triage unit sequence # **150830**

Internet Submission - Page 1

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier	2. Age at time of event: 72 Years	3. Sex: <input type="checkbox"/> female or <input checked="" type="checkbox"/> male	4. Weight: 63 lbs or kgs
In confidence Date of birth:			

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: 07/23/2001
 4. Date of this report: 09/10/2001

5. Describe event or problem
 Patient is a 72 year old male with history of peptic ulcer who presents to the ER on 7/23/01 after vomiting blood and passing black and red bloody stool. Patient took 2 aspirin to relieve foot pain, after which he became dizzy then vomitted. Patient's current medications include ranitidine 150mg qd, HCTZ 25mg qd, KCL 10meq bid, and aspirin which he has been taking 1-2 qd for the last two months. HGB and HCT were 9.6 and 28.3 respectively. Patient was admitted. Patient was given two units PRBC's. IV ranitidine was also begun

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.)

MEDWATCH
 SEP 11 2001
 CTU/150830

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler) #1 aspirin 325mg /	2. Dose/Frequency/Route used #1 325mg /bid /Oral	3. Therapy dates (if unknown give duration) #1 From - To (or best estimate)
4. Diagnosis for use (separate indicators with commas) #1 foot pain	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	
6. Lot # (if known) #1	7. Exp. date (if known) #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		
10. Concomitant medical products and therapy dates (exclude treatment of event)		

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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

5. Expiration date

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

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send device if not returned to manufacturer on **DSS**)
 yes no

10. Concomitant medical products and therapy dates (exclude treatment of event)
 SEP 12 2001

E. Reporter (see confidentiality section on back)

1. Name phone #

V.A. MEDICAL CENTER 500 W NATIONAL MILWAUKEE Wisconsin 53295 United States MED.VA.GOV

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

Individual Safety Report



VOLUNTARY reporting
health professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **150825**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [REDACTED]	2. Age at time of event: 80 Years Date of birth: _____	3. Sex female _____ <input checked="" type="checkbox"/> male	4. Weight _____ lbs or 85 _____ 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 <input checked="" type="checkbox"/>	congenital anomaly _____
hospitalization - initial or prolonged _____	required intervention to prevent permanent impairment/damage _____
	other _____

3. Date of event 06/29/2001
(mm/dd/yyyy)

4. Date of this report 09/10/2001
(mm/dd/yyyy)

5. Describe event or problem
Patient is a 80 year old male with history of hypertension and hyperlipidemia who presents to ER with complaint of lightheadedness and dark stools. Patient has been taking aspirin prophylactically. Patient was admitted. Aspirin was discontinued. EGD showed two antral ulcers.

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 (Product Name) (Labeled Strength) (Mfr/Labeler) #1 aspirin / 325mg / #2 / /	2. Dose/Frequency/Route used #1 325mg / qd / Oral #2 / /	3. Therapy dates (if unknown, give duration) #1 From To (or best estimate) #2 - -	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1 anticoagulation #2	6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # (for product problems only)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

D. Suspect medical device

1. Brand name	2. Type of device	3. Manufacturer name & address	4. Operator of device health professional _____ lay user/patient _____ other _____
6. model #	7. If implanted, give date (mm/dd/yyyy)	5. Expiration date (mm/dd/yyyy)	
catalog # MEDWATCH CTU	8. If explanted, give date (mm/dd/yyyy)	9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no returned to manufacturer on _____ (mm/dd/yyyy)	
serial #	10. Concomitant medical products and therapy dates (exclude treatment of event)		
lot #	SEP 12 2001		
other #	DSS		

E. Reporter (see confidentiality section on back)

1. Name [REDACTED]	phone # [REDACTED]
V.A. MEDICAL CENTER 5000 W NATIONAL MILWAUKEE Wisconsin 53295 United States [REDACTED] MED VA, DCV	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> 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. <input checked="" type="checkbox"/>	



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-2747
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.



150795

A. Patient information

1. Patient identifier 3484	2. Age at time of event: 53	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
Date of birth: _____			

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: _____

Date of event (m/d/yyyy): 8/16/01

Date of this report (m/d/yyyy): 8/17/01

Describe event or problem

Pt presents with 4 day H/O N/V and epistaxis x4. ⊕ coffee grounds emesis possibly from epistaxis. NGL ⊕. Pt in acute / chronic renal failure with significant uremia. EGD: duodenitis - no source of bleed. Admitted to ICU, given valproic acid, 4 units PRBCs, dialysis. Source of bleed epistaxis

Relevant tests/laboratory data, including dates

from platelet dysfunction

BUN 213 Cr 4.0 Hct 19

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

HTN, CVA, renal failure

severe possible

Mail to: MEDWATCH 3600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

SEP 10 2001

CTU 150795

C. Suspect medication(s)

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

#1 aspirin

#2

2. Dose, frequency & route used

#1 650mg QD

#2

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

#1

#2

4. Diagnosis for use (indication)

#1 CVA

#2

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1

#2

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

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (m/d/yyyy)

6. model #

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

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

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

yes no returned to manufacturer or _____ (m/d/yyyy)

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

E. Reporter (see confidentiality section on back)

1. Name, address, telephone #

Pharm D
St

2. Health professional? yes no

3. Occupation
Clinical 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.

DSS

SEP 12 2001



3791894-1-00-01

Page of

150801

A. Patient information

1. Patient identifier 8934 in confidence	2. Age at time of event: or Date of birth: 73	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	---	---	---

B. Adverse event or product problem

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

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

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

3. Date of event (m/d/yyyy): 8/22/01

4. Date of this report (m/d/yyyy): 8/24/01

Describe event or problem

pt presented to ECS with bloody bowel movements starting the day prior to admission. Pt received tagged RBC scan @ active bleeding in sigmoid colon, angiogram - no active bleeding. Surgery consulted for elective hemicolectomy - pt refused. Admitted to MICU, transfused 2 units PRBCs. Aspirin held. NG lavage @.

Relevant tests/laboratory data, including dates

RECEIVED

SEP 12 2001

MEDWATCH CTU

Hct 41 -> 26.9

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

lower GI bleed x2, AFib, CAD,
Dm, HTN, gout, prostate CA,
diverticular disease

severe possible

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

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.

SEP 10 2001

CTU 150801

C. Suspect medication(s)

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

#1 aspirin

#2

2. Dose, frequency & route used

#1 325mg QD

#2

3. Therapy dates (if unknown, give duration) (m/d/yyyy)

#1

#2

4. Diagnosis for use (indication)

#1 AFib/CAD

#2

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1

#2

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

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: _____

5. Expiration date (m/d/yyyy)

6. model # _____

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

catalog # _____

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

serial # _____

lot # _____

other # _____

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

yes no returned to manufacturer on: _____ (m/d/yyyy)

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

Pharm D
ST

2. Health professional?
 yes no

3. Occupation
Clinical 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.

SEP 12 2001



150804

A. Patient information

1. Patient identifier 1390 In confidence	2. Age at time of event: 49 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	--	---	---

B. Adverse event or product problem

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

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

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

3. Date of event (m/d/yyyy) 8/14/01	4. Date of this report (m/d/yyyy) 8/15/01
--	--

Describe event or problem

At with multiple LE vascular procedures and thrombolysis on heparin/warfarin/aspirin experienced melanic stool. At transferred to acute care setting. NGL ⊖, he ⊕ stool, EGD + NE, colonoscopy: ischemic colitis, diverticulosis. At received 6 units PRBCs 6 units FFP, raltegravir, Romasa enemas.

Relevant tests/laboratory data, including dates

RECEIVED

Hct 33 → 26
INR 4
ATT 134 (43-63) MEDWATCH CT

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

PVD, HTN, multiple LE bypass ± amputation for thrombolysis, tobacco

Severe

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20855

or FAX to:
1-800-FDA-0178

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) (month for best estimate)	
#1	warfarin/aspirin	#1	
#2	heparin	#2	
2. Dose, frequency & route used		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
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1	PVD	#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)	10. Concomitant medical products and therapy dates (exclude treatment of event)	
#1			
#2			
9. NDC # (for product problems only)			

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)	
6. Model #		7. If implanted, give date (m/d/yyyy)	
7. Catalog #		8. If explanted, give date (m/d/yyyy)	
8. Serial #			
9. Lot #			
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. Concomitant medical products and therapy dates (exclude treatment of event)			

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
Pharm D ST			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Clinical Pharmacist	
4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user society <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"/>			

SEP 10 2001

DSS

SEP 12 2001

150804



3791928-4-00-01

Page of

150827

A. Patient information

1. Patient identifier: [redacted]

2. Age at time of event: 69
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 disability

life-threatening congenital anomaly

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

other: _____

Date of event (m/d/yyyy): 7/24/01

Date of this report (m/d/yyyy): 7/25/01

Describe event or problem

At came to ECS with 3 episodes of melena associated with lightheadedness. NGL (+). Admitted to ICU, EGD: duodenal ulcer ± visible vessel and fresh food - heater probe and local epinephrine given. Rx: 6 units PRBCs, ranitidine, bismuth, metronidazole, tetracycline.

Relevant tests/laboratory data, including dates

Aspirin, ibuprofen Nc'd, changed to rofecoxib.

Hct 38 → 21.5

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

DM, prostate CA, HTN, GERD, OA, PUD ± GI bleed (80's, 90's)

DA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-0178

OR FAX to: 1-800-FDA-0178

C. Suspect medication(s)

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

#1 ibuprofen

#2 aspirin

2. Dose, frequency & route used

#1 400mg QD

#2 325 mg QD

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

#1 _____

#2 _____

4. Diagnosis for use (indication)

#1 Knee Pain

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____

#2 _____

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

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: _____

5. Expiration date (m/d/yyyy)

6. catalog # RECEIVED

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

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

serial # SEP 12 2001

lot # MEDWATCH CTU

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 #

Pharm D

St

2. Health professional? yes no

3. Occupation Clinical 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.

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.

SEP 10 2001

DSS

CTU 150827

SEP 12 2001



COVANCE

Use by user - facilities distributors and manufacturers for MANDATORY reporting

FDA Facsimile Approval 8/13/98

Mfr report #	7644890
UF/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient Identifier 7644890 In confidence	2. Age at time of event: 69 or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 300 lbs or kg
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> life-threatening	<input type="checkbox"/> hospitalization-initial or prolonged	<input checked="" type="checkbox"/> other: <u>Medically Significant</u>	
3. Date of event (mo/day/yr) 7/31/00	4. Date of this report (mo/day/yr) 11/16/00		
5. Describe event or problem Information has been received from a 69-year-old male who had taken 1 BAYER 8-Hour caplet daily for heart attack prevention from 07/07/00 to 08/01/00. On 07/31/00, the consumer experienced internal bleeding, stomach upset, sour stomach and loss of appetite. The consumer discontinued use of the product and within 1 week the bleeding subsided. On 10/05/00 all symptoms had subsided with the exception of his loss of appetite. Medical history included elevated cholesterol and prostate surgery. Concomitant therapy was not provided. If additional information is obtained, it will be forwarded.			
6. Relevant tests/laboratory data, including dates None			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) History of elevated cholesterol and prostate surgery.			

AUG 23 2001



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 8-Hour BAYER. Caplets - 72s			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 1 ORAL 01X/D		#1 7/7/00 - 8/1/00	
#2		#2	
4. Diagnosis for use (indication)			5. Event abated after use stopped or dose reduced
#1 Heart Attack Prevention			#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a
#2			#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a
6. Lot # (if known)		7. Exp. date (if known)	
#1 SO14HF		#1 111992	
#2		#2	
9. NDC #-for product problems only (if known)			
#1			
#2			
10. Concomitant medical products and therapy dates (exclude treatment of event) None Provided			

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
4. Date received by manufacturer (mo/day/yr) 10/5/00	3. Report Source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
5. (A)NDA # 16 - 030	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 # 0	8. Adverse event term(s) GASTROINTESTINAL HEMORRHAGE; DYSPEPSIA; ANOREXIA
9. Mfr. report number 7644890	

E. Initial reporter			
1. Name, address & phone # [redacted] [redacted] Drive [redacted]			
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	



3792804-3-00-01

257

DA 151084

ADR Report for FDA: 3rd - 4th QTR. 2000

██████████ Hospital ██████████ Region, ██████████ Road, ██████████

Med Rec #: 190902 Age: 084 Sex: M Rxn Date: 08/20/2000

ADR: GI BLEED Medication: ASPIRIN

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

Comments:

Diagnosis:

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

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SEP 13 2001
MEDWATCH CTU

DSS
SEP 14 2001

CTV151084

Individual Safety Report

VOLUNTARY reporting
alth professionals of adverse
nts and product problems



3793355-2-00-01

Page ___ of ___

Form Approved: OMB No. 0910-0001 Expires 12/31/02
See OMB statement on reverse

FDA Use Only

FD-1085 (Rev. 10/00)
FD-1085 (Rev. 10/00)
151164

A. Patient information

1. Patient identifier 4285 in confidence	2. Age at time of event or Date of birth: 72	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight lb or kg 89.8
--	---	---	----------------------------------

B. Adverse event or product problem

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

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)
2/26/01

4. Date of this report (m/d/yyyy)
7/31/01

5. Describe event or problem

pt admitted with dark stools + some nausea. His ibuprofen was bid and his prednisone tapered. He was transferred to another hospital and found to have a gastric ulcer with H. Pylori. PT treated for H. Pylori and now takes Celebrex for his B.A.

Relevant tests/laboratory data, including dates

2/26
Heme @ stool
Hq = 13.3
HCT = 39.7

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

RA COPD
HTN
hyperlipidemia
hx DVT's

C. Suspect medication(s)

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

#1 Ibuprofen (600mg) / ASA ec.
#2 Prednisone 5mg 30mg/day

2. Dose, frequency & route used

#1 600mg po QID PRN
#2 20mg/day

3. Therapy dates (if unknown, give duration)

#1 ?
#2 ?

4. Diagnosis for use (indication)

#1 Arthritis
#2 ?

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot # (if known)

#1
#2

7. Exp. date (if known)

#1
#2

8. NDC # (for product problems only)

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

Combivent lisinopril Triamcinolone cream
lasix nifedipine Silvadene cream
lactulose metamucil

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional
 lay user/patient
 other

5. Expiration date (m/d/yyyy)

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

7. If explanted, 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)

SEP 14 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

Pharm D
VA Med Center 119
2200 Gage
Topeka, KS 66622

2. Health professional? yes no

3. Occupation
Rph

4. Also reported to

manufacturer
 user facility
 distributor

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

DA Mail to: MEDWATCH
5800 Fishers Lane
Rockville, MD 20852-9787
1-800-FDA-1088

CTV151164
SEP 14 2001
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Individual Safety Report



3793391-6-00-01

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Voluntary reporting health professionals of adverse events and product problems

Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

FDA Use Only

Triage unit sequence # 157188

A. Patient information

1. Patient Identifier, 2. Age at time of event, 3. Sex, 4. Weight

B. Adverse event or product problem

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

3. Date of event, 4. Date of this report

5. Describe event or problem: Pt was admitted due to c/o BRBPR and possible episodes of melanic stools over the previous 2-3 months.

6. Relevant tests/laboratory data, including dates: 5/29/10: hgb/Hct=8.4/24.8

7. Other relevant history, including preexisting medical conditions

C. Suspect medication(s)

1. Name (Product Name), 2. Dose/Frequency/Route used, 3. Therapy dates, 4. Diagnosis for use, 5. Event abated after use, 6. Lot #, 7. Exp. date, 8. Event reappeared after reintroduction, 9. NDC #, 10. Concomitant medical products

D. Suspect medical device

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

E. Reporter (see confidentiality section on back)

1. Name, 2. Health professional?, 3. Occupation, 4. Also reported to, 5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.

MEDWATCH 2007 SEP 14 2001

5600 Fishers Lane, Rockville, MD 20851-9787, 1-800-FDA-0178

FDA Form 3500

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

Individual Safety Report



Voluntary reporting with professionals of adverse events and product problems

Form Approved OMB No. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

151190

Internet Submission - Page 1

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier: [redacted] In confidence

2. Age at time of event: 82 Years
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 (mm/dd/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (mm/dd/yyyy): 05/06/2001

4. Date of this report (mm/dd/yyyy): 09/12/2001

5. Describe event or problem
Pt was admitted with 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.)

MEDWATCH
SEP 13 2001
CFV 151190
RECEIVED

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
#1 Aspirin / 325 mg /
#2 / /

2. Dose/Frequency/Route used
#1 325 mg / daily / Oral
#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 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)
ISDN; levofloxacin; metoprolol; ranitidine; sertraline; simvastatin; terazosin

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 # SEP 14 2001
catalog # MEDWATCH CTU
serial #
lot #
other #

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

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

9. Device available for evaluation? (Do not send device to FDA)
 yes no **DSS** returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)
SEP 14 2001

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone [redacted]
[redacted] PharmD
VA Pittsburgh Healthcare System -132M-H-, 7180 Highland Drive
Pittsburgh Pennsylvania 15206
United States [redacted].va.gov

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

Individual Safety Report



3793468-5-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **157218**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient identifier: [redacted] In confidence

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

3. Sex: female male

4. Weight: [redacted] lbs or [redacted] kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply):
 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: 06/10/2001 (mm/dd/yyyy)

4. Date of this report: 09/12/2001 (mm/dd/yyyy)

5. Describe event or problem
 Admitted after presenting with c/o melena and progressive orthostasis x 10 days. Worked up for probably 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.)
 PUD; HTN; ticuspid regurgitation; mitral regurgitation; hyperlipidemia; hx CVA; glucose intolerance

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 Aspirin / /
 #2 / /

2. Dose/Frequency/Route 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 CVA
 #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
 #1 #2

7. Exp. date (if known) #1 #2
 #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)
 fleodipine; terazosin; lisinopril

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 # SEP 14 2001
 catalog # MEDWATCH CTU
 serial #
 lot #
 other #

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

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

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

10. Concomitant medical products and therapy dates (exclude treatment of event)
 DSS
 SEP 17 2001

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]
 [redacted] PharmD
 VA Pittsburgh Healthcare System -132M-H-, 7180 Highland Drive
 Pittsburgh Pennsylvania 15206
 United States [redacted] ed.va.gov

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 or FAX to: 1-800-FDA-0178

MEDWATCH

CTV 157218 SEP 14 2001

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Individual Safety Report



3794037-3-00-01

Voluntary reporting
by professionals of adverse
drug and product problems

Internet Submission - Page 1

Form Approved OMB No. 0510-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

157380

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [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: 07/13/2001

4. Date of this report: 09/12/2001

5. Describe event or problem

Pt was transferred from Altoona VAMC for management of upper GI bleed. Pt took ASA and celecoxib 7/12/01 and developed hematemesis, abdominal distention, and ascites.

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.)
end-stage liver dz secondary to chronic alcoholic cirrhosis; Parkinson's dz; depression; anxiety; PTSD; DM; BPH; HTN

MEDWATCH

SEP 17 2001

CTV 157380



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

RECEIVED

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 (Product Name) #1 Aspirin / 325 mg	(Labeled Strength)	(Mfr/Labeler)
#2 Celebrex /		
2. Dose/Frequency/Route used #1 325 mg / daily / Oral	3. Therapy dates (if unknown, give duration) From To (or best estimate)	#1 - -
#2 / daily / Oral		#2 - -
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced	
#1	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2	#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	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		
10. Concomitant medical products and therapy dates (exclude treatment of event)		

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
5. Expiration date (mm/dd/yyyy)	6. model #
7. If implanted, give date (mm/dd/yyyy)	7. RECEIVED
8. If explanted, give date (mm/dd/yyyy)	catalog #
	SEP 17 2001
	serial #
	lot #
	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	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section or back)

1. Name	phone #
PharmD VA Pittsburgh Healthcare System -132M-H-, 7180 Highland Drive Pittsburgh, Pennsylvania 15206 United States med.va.gov	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist
4. Also reported to <input type="checkbox"/> manufacturer <input 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"/>	

Individual Safety Report



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

Internet Submission Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

151376

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier	2. Age at time of event: 58 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) 07/25/2001

4. Date of this report (mm/dd/yyyy) 09/12/2001

5. Describe event or problem
Pt presented with complaint of black tarry stools. Admitted for 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.)
T9 paraplegia after gunshot wound; carcinoma of rectum, status post excision and colostomy

MEDWATCH

SEP 17 2001



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

RECEIVED

C. Suspect medication(s)

1. Name (Product Name) #1 Aspirin / 325 mg (Labeled Strength)	(Mfr/Labeler)
2. Dose/Frequency/Route used #1 325 mg / daily / Oral	3. Therapy dates (if unknown, give duration) #1 From - To (or best estimate)
4. Diagnosis for use (separate indications with commas) #1	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
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 checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only)	8. Event reappeared after reintroduction #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) tmp-smx SS; alprostadil	

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. model # SEP 17 2001

6. catalog # MEDWATCH CTU

7. serial #

8. lot #

9. other #

9. Device available for evaluation? yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)
SEP 18 2001

E. Reporter (see confidentiality section on back)

1. Name phone #

PharmD
VA Pittsburgh Healthcare System -132N-H-, 7180 Highland Drive
Pittsburgh, Pennsylvania 15206
United States med.va.gov

2. Health professional? yes no

3. Occupation Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

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

Individual Safety Report



VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **151377**

Internet Submission - Page 1

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

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

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply): death (mm/dd/yyyy) life-threatening hospitalization - in trial or prolonged disability congenital anomaly required intervention to prevent permanent impairment/damage other: _____

3. Date of event (mm/dd/yyyy) 07/18/2001 4. Date of this report (mm/dd/yyyy) 09/12/2001

5. Describe event or problem
Pt resident at NECU. Pt found to have Hgb of 4.9; determined to have a GI bleed. Was transferred to med/surg facility.

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.)
DM; anemia; dementia; end stage renal dz; COPD; adrenal insufficiency

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
#1 Aspirin / 325 mg /
#2 Heparin / 5000 units /

2. Dose/Frequency/Route used
#1 325 mg / daily / Oral
#2 5000 units / BID / Subcutaneous

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 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 (mm/dd/yyyy)

6. model # MEDWATCH CTU
catalog #
serial #
lot #
other #

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

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

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

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

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted] PharmD
VA Pittsburgh Healthcare System -132M-H-, 718C Highland Drive
Pittsburgh Pennsylvania 15206
United States [redacted] med, va.gov

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 20855 or FAX to: 1-800-FDA-0178

MEDWATCH

SEP 17 2001

CTV151377

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623

Individual Safety Report



3795605-5-00-01

DLUNTARY reporting
h professionals of adverse
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FD-108 (Rev. 1/01)	157527
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Page ___ of ___

THE FDA MEDICAL PRODUCT REPORTING PROGRAM

A. Patient information			
1. Patient identifier 908398 <small>In confidence</small>	2. Age at time of event: 72 or Date of birth: [redacted]	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 <input type="checkbox"/> Product problem (e.g., defects, malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	<input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____

3. Date of event 1/16/01	4. Date of this report 9/4/01
-----------------------------	----------------------------------

5. Describe event or problem

Pt. experienced rectal bleeding about 6 hours after stent placement. Given PRBC's. Underwent colonoscopy. Found to have angiodysplasia. Since risk of bleeding was high if patient was to continue on aspirin & Plavix, she eventually underwent a right hemicolectomy. She was discharged 1/26/01.

6. Relevant tests/laboratory data, including dates

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

Peripheral vascular disease
Cigarette smoking

CTU 157527



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.

C. Suspect medication(s)			
1. Name (give labeled strength & manufacturer, if known)		3. Therapy dates (if unknown, give duration)	
#1 Aggrastat		#1 1/16/01	
#2 Plavix, aspirin		#2 1/16/01	
2. Dose, frequency & route used		4. Diagnosis for use (indication)	
#1 0.1 mcg/kg/min		#1 Non-wave MI	
#2 81mg qd		#2 Non-q-wave MI	
5. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
6. NDC # (for product problems only)		8. Event abated after use stopped or dose reduced	
#1		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. Event reappeared after reintroduction		10. Concomitant medical products and therapy dates (exclude treatment of event)	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		Nitroglycerin, heparin, Activan prn, Lopressor	
#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply			

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 (if applicable)	
7. If implanted, give date (if applicable)	
8. If explanted, give date (if applicable)	
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)		
1. Name, address & phone #		
[redacted] St		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Clinical Coordinator Pharmacy	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> insurer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		

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DSS

SEP 19 2001

Individual Safety Report



3797848-3-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 04/30/03
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FDA Use Only

Trace unit
sequence # 151959
faxed to Ruman Bannick

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier 2571 In confidence	2. Age at time of event: 55 Years or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or 87 kgs
--	---	---	------------------------------------

B. Adverse event or product problem

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

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

<input checked="" type="checkbox"/> death 04/02/2001 (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 04/02/2001 (mm/dd/yyyy)

4. Date of this report 09/21/2001 (mm/dd/yyyy)

5. Describe event or problem

Patient with significant ETOH abuse and no h/o medical care x 30 years self medicating with OTC aspirin admitted with Gastrointestinal bleed from which he died.

6. Relevant tests/laboratory data, including dates

DSS
SEP 25 2001

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

MEDWATCH
SEP 24 2001

CTU 151959 RECEIVED

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler) #1 Aspirin / Unknown /	2. Dose/Frequency/Route used #1 Unkno / Unknow / Oral	3. Therapy dates (if unknown, give duration) #1 From - To (or best estimate)
4. Diagnosis for use (separate indications with commas) #1 GI Pain	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	6. Lot # (if known) #1
7. Exp. date (if known) #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)		

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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SEP 24 2001
MEDWATCH CTU

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

5. Expiration date (mm/dd/yyyy)

6. model # _____
catalog # _____
serial # _____
lot # _____
other # _____

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

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

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

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

E. Reporter (see confidentiality section on back)

1. Name _____ phone _____

Pharm D
VA PSHCS, 1660 South Columbian Way
Seattle Washington 98108
United States med.va.gov

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



#3798050-1-00-01*

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SEP 24 2001

THE FDA MEDICAL PRODUCTS REPORTING SYSTEM

A. Patient information

1. Patient Identifier 00358 in confidence	2. Age at time of event: 74 yrs or Date of birth:	3. Sex female <input type="checkbox"/> male	4. Weight NI lbs or NI 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):
 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) 08/11/2001

4. Date of this report (mo/day/yr) 08/30/2001

5. Describe event or problem

Initial Notification (27-Aug-01)

A 74-year-old male was diagnosed with a GASTRIC ULCER POSSIBLY RELATED TO VIOXX. He has had chronic atrial fibrillation and had begun taking Coumadin (warfarin sodium) on an unspecified date. He also took aspirin 81 mg beginning in 1983 and Vioxx (rofecoxib) 25 mg beginning on 8-Jun-01 until 11-Aug-01, when both medications were discontinued. He is currently enrolled in the ACTION study and has been taking Coumadin 1.25 mg for 6 days and 2.5 mg for 1 day a week since 24-Aug-01.

On 11-Aug-01, the patient presented to the emergency room with complaints of *

6. Relevant tests/laboratory data, including dates

11-AUG-2001	Hemoglobin	4.1
11-AUG-2001	Hematocrit	14.5
11-AUG-2001	Sodium	139
11-AUG-2001	Potassium	4.9
11-AUG-2001	International Normalized Ratio	4.0 (target 1.5-2.0) *

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

Chronic AF
 CVA, seizure disorder secondary to CVA
 Ventricular septal defect
 Open heart (1962)
 *SBE" (1983) *

C. Suspect medication(s)

1. Name (give trade name, generic name, labeler, if known)	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 COUMADIN (Crystalline Warfarin Sodium)	#1 NI, continuing
#2 VIOXX (ROFECOXIB)	#2 08-JUN-2001 to 11-AUG-2001
2. Dose, frequency & route used	5. Event abated after use stopped or dose reduced
#1 UNK UNK PO	#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> doesn't apply
#2 25 MG UNK UNK	#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> doesn't apply
4. Diagnosis for use (indication)	8. Event reappeared after reintroduction
#1 ATRIAL FIBRILLATION	#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> doesn't apply
#2 UNKN CAUSE MORB/MORT NEC	#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 NI	#1 NI
#2 NI	#2 NI
9. NDC # - for product problems only (if known)	
#1 NI	#2 NI
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NI	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
DuPont Pharmaceuticals Company Chestnut Run Plaza, HR1132 P.O. Box 80723 Wilmington DE 19880-0723 USA	(302) 892-0694
4. Date received by manufacturer (mo/day/yr)	5. (A)NDA #
08/27/2001	9-218
6. If IND, protocol #	7. Type of report (check all that apply)
	5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #
9. Mfr. report number	8. Adverse event term(s)
2001COU1517	CHEST PAIN, GASTRIC ULCER, ASTHENIA, CONFUSION, MELAENA, ANAEMIA, PROTHROMBIN DECREASED

E. Initial reporter

1. Name, address & phone #
 Ms. _____ Clinic, _____ Med Bldg _____ Ave _____
 _____ USA
 Phone: _____

2. Health professional? yes no
 3. Occupation _____
 4. Initial reporter also sent report to FDA yes no unk



Domain Facsimile of FDA Form 3500A

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

SEP 24 2001



A. Patient information

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

B. Adverse event or product problem

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

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

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

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

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

5. Describe event or problem

C. Suspect medication(s)

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

#3 ASA (ACETYSALICYLIC ACID)

#4

2. Dose, frequency & route used

#3 81 MG UNK UNK

#4

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

#3 ??-??-1983 to 11-AUG-2001

#4

4. Diagnosis for use (indication)

#3 UNKN CAUSE MORB/MORT NEC

#4

5. Lot # (if known)

#3 NI

#4

6. Exp. date (if known)

#3 NI

#4

7. Event abated after use stopped or dose reduced

#3 yes no doesn't apply

#4 yes no doesn't apply

8. Event reappeared after reintroduction

#3 yes no doesn't apply

#4 yes no doesn't apply

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

#3 NI

#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. 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 type="checkbox"/> 15-day	<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	<input type="checkbox"/> consumer
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up #	<input type="checkbox"/> health professional
9. Mfr. report number	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	other: _____

5. (A)NDA # _____

IND # _____

PLA # _____

pre-1938 yes no

OTC product yes no

8. Adverse event term(s)

E. Initial reporter

1. Name, address & phone #

2. Health professional? yes no

3. Occupation _____

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.
* Item completed on continuation pages.

SEP 25 2001

SEP 24 2001

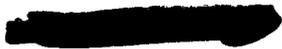


A.1. Patient Identifier

G.9. Mfr. report number

2001COU1517

MED WATCH



B.5. Describe event or problem

[continuation:] WEAKNESS, CONFUSION, and CHEST PRESSURE. Laboratory evaluations included GUIAC-POSITIVE STOOLS, HGB 4.1 and INR 4.0 (target 1.5-2). He was hospitalized and REQUIRED MULTIPLE UNITS OF PRBCs and vitamin K. An endoscopy performed on 13-Aug-01 revealed a 2 cm gastric ulcer in the distal antrum that was not actively bleeding. He recovered on an unspecified date.

Study Title: ACTION - Anticoagulation Consortium To Improve Outcomes Nationally, a Phase IV, Health Economics Study (946-910).

B.6. Relevant tests/laboratory data, including dates

[continuation:] 11-AUG-2001 Other
Troponin 1 (#1) <0.10
11-AUG-2001 Other
ECG paced rhythm

13-AUG-2001 Endoscopy
Gastric ulcer on distal antrum - lesser curve aspect and not actively bleeding.

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

[continuation:] Colon cancer (1982)

E.3. Occupation

Other Health Professional

SEP 24 2001

Individual Safety Report



3799228-3-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Voluntary reporting by health professionals of adverse events and product problems

Page 1 of 1

Form Approved, OMB No. 0910-0201 Expires 04/30/03

FDA Use Only

Trigger unit sequence #

152245

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event or Date of birth: [Redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 257 lbs or [Redacted] 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 (mortality)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year) 8/9/01	4. Date of this report (month/year) 9/25/01
---	--

5. Describe event or problem
 Pt admitted to ER due to bleeding from bowel. Also vomitted blood. Endoscopy performed & found gastric and duodenal ulcers with visible vessel & normal erosions secondary to NSAIDs & wide-based non-bleeding duodenal ulcer.

6. Relevant tests/laboratory data, including dates
 8/9/01 - endoscopy (results above).
 Hemoglobin = 13
 H. pylori test - positive

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 African-American
 HTN, coronary artery disease, asthma
 osteoarthritis - Bilateral - knees
 1/2 PPD smoking history
 SEP 20 2001
 CTK152245

C. Suspect medication(s)

1. Name (give labeled strength & rpr/labeler, if known)	
#1 Celebrex - Pfizer	
#2 Enteric-coated Aspirin	
2. Dose, frequency & route used	
#1 200mg PO BID	#3 Therapy dates (if unknown, give duration) (month/year or best estimate)
#2 325mg PO QD	#1 1/01 - 8/01
	#2 at least 3/98 - 8/01
4. Diagnosis for use (indication)	
#1 osteoarthritis	5. Event abated after use stopped or dose reduced
#2 MI prevention	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2
9. NDC # (for product problems only)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
Lipitor - prior to event	
Maxzide " " "	
Lopressor " " "	

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	
RECEIVED SEP 26 2001 MEDWATCH CTU	
4. Operator of device	5. Expiration date (month/year)
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other:	
6. model #	7. If implanted, give date (month/year)
catalog #	
serial #	
lot #	8. If explanted, give date (month/year)
other #	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes	<input checked="" type="checkbox"/> returned to manufacturer on _____ (month/year)
10. Concomitant medical products and therapy dates (exclude treatment of event)	
SEP 26 2001	

E. Reporter (see confidentiality section on back)

1. Name & address		phone #
[Redacted]		[Redacted]
[Redacted] PHARM.D. [Redacted] FAMILY PRACTICE [Redacted] ST		
2. Health professional?	3. Occupation	4. Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	PHARMACIST	<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"/>		

PLEASE TYPE OR USE BLACK INK



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

Individual Safety Report



3799399-9-00-01

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

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

FDA Use Only

Triage unit
sequence #

152403

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event: 85 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 160 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 checked="" type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (mo/day/yr) 5/5/01

4. Date of this report (mo/day/yr) 9/20/01

5. Describe event or problem

GI bleeding 20 Celebrex + baby Aspirin on adm. EG Deep gastric ulcer on SM Small partial hernia Given Pepacid 20mg IV q 12h 300mg, iron pid No aspirin OR Celebrex

6. Relevant tests/laboratory data, including dates

Hemoglobin 9.6
Hematocrit 28.1

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

Prostate Cancer, HTR
S/P CABG 1997

C. Suspect medication(s)

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

#1 Celebrex
#2 Aspirin

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)

on radiation for prostate CA

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 or

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

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SEP 26 2001
MEDWATCH CTU

DSS

SEP 27 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[Redacted]

2. Health professional? yes no

3. Occupation: Medical Rep

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



Human Health Division

Use by user-facilities,
wholesalers and manufacturers for
MANDATORY reporting

Merck Facsimile of FDA Form 3500A
Approved by FDA (1/02/93)

The FDA Medical Products Reporting Program

Mfr report #	WAES 01071078
UH/Usr report #	
FDA Use Only	

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: or 68 years Date of Birth: [redacted]	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight Unk
-------------------------------------	--	---	------------------

B. Adverse event or product problem

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

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

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

3. Date of event (mo/day/yr) 00? 4. Date of this report (mo/day/yr) 09/19/01

5. Describe event or problem

Information has been received from a 68 year old female with no known allergies who in approximately July 2000 was placed on therapy with rofecoxib, 25 mg tablet, 25 mg, once a day for the treatment of osteoarthritis (duration not reported). Concomitant therapy included aspirin. In approximately 2000 the patient developed esophageal ulcers. Her physician thought the esophageal ulcers were caused by uncoated aspirin and he switched her to coated aspirin. Subsequently, the patient recovered from esophageal ulcers. The patient developed minor swelling in her ankles "from time to time". The physician felt that the esophageal ulcers were not related to therapy with rofecoxib.

Additional information has been requested.

8. Relevant tests/laboratory data, including dates
Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
None

C. Suspect medication(s)

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

1 TAB VIOXX 25 mg

2 aspirin Unk

2. Dose, frequency & route used

1 25 mg/DAILY/PO

2 Unk/Unk/Unk

3. Therapy dates (from/to); if unknown, give duration

1 07??/??/00 - Cont

2 Unk - Unk

4. Diagnosis for use (indication)

1 osteoarthritis

2 Unknown

5. Event abated after use stopped or dose reduced.

yes	no	N/A	unk
# 1 <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
# 2 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

1 _____ # 1 _____

2 _____ # 2 _____

8. Event reappeared after reintroduction

yes	no	N/A	unk
# 1 <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
# 2 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

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

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number
(610)397-2416

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) 07/11/01

5. (ANDA # 21042)

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

9. Mfr. report number
WAES 01071078

8. Adverse event term(s)
ESOPHAGEAL ULCER; LOWER EXTREMITY ED/MA

E. Initial reporter

1. Name, address & phone #
Confidential Report
[redacted]

2. Health professional?
 yes no

3. Occupation

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

FDA

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

SEP 24 2001

Individual Safety Report



3803406-4-00-01

For VOLUNTARY reporting
health professionals of adverse
events and product problems

Page ___ of ___

FDA Use Only

Triage unit sequence # 152872

A. Patient information:

1. Patient identifier #1537 In confidence	2. Age at time of event: 52 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 (m/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/day/yr) 7/31/01

4. Date of this report (m/day/yr) 8/10/01

5. Describe event or problem

H/O 2 DAYS NV, epigastric pain (hematemesis)

TX = Sandostatin 50mcg bolus, followed by 50mcg/hr.

Ranitidine 50mg IV qh

Lansoprazole.

FFP Jumbo.

6. Relevant tests/laboratory data, including dates

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

EtOH use

H. pylori +

CTV 152872

C. Suspect medication(s):

1. Name (give labeled strength & mfr/labeler, if known)		
#1	VIOXX	
#2	Ibuprofen (OTC) and Aspirin	
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from start to best estimate)
#1	25mg qd	#1 4 DAYS
#2	600mg qd?	#2
4. Diagnosis for use (including ICD-9)		5. Event abated after use stopped or dose reduced
#1	650 8 4 PR	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply
#2	OSTEOARTHRITIS PAIN	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply
6. Lot # (if known)	7. Exp. date (if known)	
#1	#1	
#2	#2	
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
<p>RECEIVED</p> <p>OCT 02 2001</p> <p>MEDWATCH CTU</p>	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
	5. Expiration date (m/day/yr)
	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)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (m/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

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

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

E. Reporter (see confidentiality section on back):

1. Name, address & phone # [redacted]		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation PCL	4. Also reported to <input type="checkbox"/> manufacturer

Individual Safety Report



3803425-8-00-01

Form Approved: OMB No. 0910-0291

MEDWATCH

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

Mfr report #	153000 -
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event	3. Sex	4. Weight
[REDACTED]	or DOB: [REDACTED]	[] female [X] male	180 lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. [X] Adverse Event and/or [] Product problem			
2. Outcomes attrib. to event		[] disability	
[] death		[] congen anomaly	
(no/day/yy)		[] required intervention to	
[] life-threatening		prevent perm impair/damage	
[X] hospitalization -		[] other:	
initial or prolonged			
3. Date of event	07/01/2001	4. Date of this Rept	09/27/2001
5. Describe event or problem			
Duodenal ulceration of sudden onset of symptoms. The patient presented to the ER on 07/01 with hematemesis of coffee ground like material. Also had melena and BRBPR. The patient was admitted and the naproxen discontinued. He was managed as an inpatient and discharged in stable condition and is now on rabeprazole.			
6. Relevant tests/laboratory data, including dates			
EGD and colonoscopy 07/03/2001 - stomach showed chronic gastritis. Duodenum showed a single non-bleeding focal superficial ulcer.			
7. Other relevant history, including preexist. med. conditions			
HTN, GERD, Generalized musculoskeletal aches and pains.			

CTU 153000

MED INFO ASSOC
Facsimile Form 3500A

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

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 Naproxen			
#2 Aspirin			
2. Dose, frequency & route		3. Therapy dates (if unk, give dur)	
#1 500 mg BID PO		#1 12/01/2000 - 07/01/2001	
#2 325 mg QD		#2 Unknown	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Musculoskeletal aches and pains		#1 [X]yes []no []N/A	
#2		#2 [X]yes []no []N/A	
6. Lot # (if known)	7. Exp. Date	8. Event reappeared after reintroduction	
#1	#1	#1 []yes []no [X]N/A	
#2	#2	#2 []yes []no [X]N/A	
9. NDC # for prod problems only			
#1			
#2			
10. Concomitant medical products and therapy dates			
Felodipine, Lisinopril, Metoprolol, Hydrochlorothiazide			
D. SUSPECT MEDICAL DEVICE			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of Dev.	
<p style="text-align: center; font-size: 2em; font-weight: bold;">RECEIVED</p> <p style="text-align: center;">OCT 03 2001</p> <p style="text-align: center; font-size: 1.5em; font-weight: bold;">MEDWATCH CTU</p>		[] Hlth Profes.	
		[] lay user/pat.	
		[] other:	
6. Model#		5. Expiration Date	
catalog#		7. If implanted, give date	
serial#		8. If removed, give date	
lot#			
other#			
9. Device available for evaluation? (Do not send to FDA)			
[] yes [] no [] returned to mfr on			
10. Concomitant medical products and therapy dates			

E. INITIAL REPORTER			
1. Name, address & phone #			
VAMC [REDACTED] 2250 Leestown Rd Pharmacy Service CDD119 Lexington, KY 40511 Phone: [REDACTED]			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
[X] yes [] no	Pharmacist	[]yes []no [X]unk	

OCT 03 2001

Individual Safety Report



3803566-5-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

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

FDA Use Only

Triage unit
sequence # **153004**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient identifier: **5679**
In confidence

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

3. Sex: female male

4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply):
 death (m/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): **7/29/01**

4. Date of this report (m/day/yr): **9/21/01**

5. Describe event or problem:

adr desc
70 YOF adm on 7/30 for GI bleed. Pt w/hx of diverticulosis who awoke from sleep, went to bathroom, & produced little or no stool, mostly blood. Mult episodes during the night. Pt lightheaded upon standing, (+) SOB upon climbing stairs with exertion. CP relieved by 3 SL NTG. On 7/30, pt with normal BM but BRBPR. MD sent pt to ED. VS: 153/104, 63, 18, 98.6, Hgb=12.1, HCT=37, Plt=144. NG lavage in ED (-) blood. Omeprazole started. ASA on hold. Colonoscopy revealed large internal hemorrhoids, multiple small scattered diverticula. Diverticulosis most extensive and most severe in sigmoid colon. Colonoscopy otherwise nml. Endoscopy revealed small hiatal hernia and evidence of erosive gastritis, erosion in the pylorus which is all likely to be NSAID injury.

C. Suspect medication(s)

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

2. Dose, frequency & route used
#1 **81mg PO QD**
#2 _____

3. Therapy dates (if unknown, give duration) (month for best estimate)
#1 **PTA**
#2 _____

4. Diagnosis for use (indication)
#1 **CAD**
#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)
O2 PRN, alendronate, isosorbide mononitrate, furosemide metoprolol, famotidine, potassium chloride hydroxychloroquine, prednisone, diltiazem, flunitrazepam

D. Suspect medical device

1. Brand name _____

2. Type of device _____

3. Manufacturer name & address _____

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

5. Expiration date (m/day/yr) _____

6. model # _____
catalog # _____
serial # _____
lot # _____
other # _____

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

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

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

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

6. Relevant tests/laboratory data, including dates

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MEDWATCH CTU

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

**Allergies: Iodine, PCN, sulfa
AMH SLE, CAD, s/p wth, diverticulosis
pulmonary fibrosis**

CTU 153004

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
**PharmD
Hospital _____
Department of Pharmacy Services
Street _____
Phone: _____**

2. Health professional? yes no

3. Occupation
Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

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

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

or FAX to:
1-800-FDA-0178

Individual Safety Report



3803873-6-00-01

Best Copy

...LUNARY reporting...
...in profess... of...
...nts and product problems

Form Approved OMB No. 0910-0281 Expires 1-3-04 See OMB Statement on...

FDA Use Only (4B)

Trace unit sequence # 152944

Page ___ of ___

A. Patient information

1. Patient identifier #1 739	2. Age at time of event 73	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ___ lbs or ___ kgs
---------------------------------	-------------------------------	---	---------------------------------------

B. Adverse event or product problem

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

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

- death
- life-threatening
- hospitalization - initial or prolonged
- disability
- congenital anomaly
- required intervention to prevent permanent impairment/damage
- other

5. Date of event (month/year) 10-10-00

6. Date of this report (month/year) 10-14-00

Describe event or problem

Aspirin induced
abdominal pain
with resultant
GI bleeding

Relevant tests/laboratory data, including dates

10/10/00
10/11/00
10/12/00

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

Aspirin induced abdominal pain due to previous GI bleeding and mild

C. Suspect medication(s)

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

#1 ASA 325mg (unit?)

#2

2. Dose, frequency & route used

#1 325mg PO QD

#2 and PRN

3. Therapy dates (if unknown, give start/stop or best estimate)

#1 9-00 - Present

#2

4. Diagnosis for use (indication)

#1 Anticoagulation

#2 (P4 used for Pain)

5. Event abated after use 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)

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

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other

5. Expiration date (month/year)

6. model #

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

8. If explanted, give c (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)

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OCT 02 2001

MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. Name & address phone #

VAMC
1500 N Washington Blvd
Poplar Bluff MO 63901

2. Health professional? yes no

3. Occupation

Pharm

4. Also reported to

manufacturer

user facility

distributor

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



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

or FAX to:
1-800-FDA-0178



GLAXOSMITHKLINE
 CONSUMER HEALTHCARE
 P. O. BOX 1467
 PITTSBURGH PA 15230 US
 1-800-245-1040

Approved by FDA on 12/1/1993	
Mfr report #	2001023207-1
UF/Dist report #	

A. Patient Information				C. Suspect Medication(s)	
1. Patient Identifier [Redacted]	2. Age at time of event: or 90 YEARS Date of birth: [Redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 130 lbs or 59 kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 ECOTRIN REGULAR STRENGTH TABLETS SMITHKLINE BEECHAM CONSUMER HEALTHCARE	
B. Adverse event or product problem				2. Dose, frequency & route used #1 325 MILLIGRAMS 1.0 DAILY ORAL	3. Therapy dates (if unk, give duration) #1 14.0 YEARS (APPROX)
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g. defects/malfunctions)				2. Diagnosis for use (indication) #1 "HEART PROBLEM"	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. Outcomes attributed to adverse event (check all that apply) <input type="checkbox"/> death (mo/day/year) <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: _____				6. Lot # (if known) #1 #2	7. Exp. Date (if known) #1 #2
3. Date of event (mo/day/year)		4. Date of this report (mo/day/year) 10/02/2001		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
5. Describe event or problem The 90 year old consumer reported that she was started on Ecotrin Regular Strength Tablets, 1 tablet daily, about 16 years ago right after she had a heart attack and angioplasty. About six months after the angioplasty she had rectal polyps removed through abdominal surgery since "they could not get the polyps out through the rectum." On October 12, 1998, she had triple bypass heart surgery due to having chest pain. She had additional abdominal surgery approximately 3 years ago due to "strangulation of a ruptured naval." Anemia was diagnosed by her doctor 2 to 3 years ago. She had a test done through her throat and a colonoscopy to determine the cause of the anemia. The tests indicated that she had a polyp in her rectum and that her stomach was irritated. She was losing blood from her stomach lining. She was hospitalized for 4 days at which time she received 2 pints of blood. The doctor decreased her Ecotrin dosage to 81 mg daily because the 325 mg dose was too strong. At the time of the report, the consumer was still taking 81 mg of Ecotrin daily without any problems. She was also taking an iron pill and Lasix (furosemide) and the anemia was resolved.					
9. NDC # - for product problems only (if known)					
10. Concomitant medical products and therapy dates (exclude treatment of event) DIGITALIS					
G. All manufacturers					
1. Contact office - name/address (& mailing site for devices) GLAXOSMITHKLINE CONSUMER HEALTHCARE P. O. BOX 1467 PITTSBURGH PA 15230 US				2. Phone number 1-800-245-1040	
4. Date r'cvd by manufacturer (mo/day/year) 09/28/2001				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 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:	
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up#				8. Adverse event term(s) ANEMIA CHEST PAIN LOSING BLOOD FROM STOMACH LINING RECTAL POLYPS RECTAL POLYPS (SECOND EPISODE) STOMACH WAS IRRITATED STRANGULATION OF A RUPTURED NAVAL	
6. Relevant tests/laboratory data including dates					
9. Mfr. report number 2001023207-1					
7. Other relevant history, including preexisting medical conditions (Cont'd) (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) HEIGHT (ins): 59					
E. Initial Reporter					
1. Name, address & phone # [Redacted] CONSUMER [Redacted] [Redacted]					
2. Health Professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		3. Occupation		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

DSS

OCT 11 2001

OCT 10 2001



3808271-7-00-02

GLAXOSMITHKLINE
CONSUMER HEALTHCARE
P. O. BOX 1467
PITTSBURGH PA 15230 US
1-800-245-1040

Approved by FDA on 12/1/1993	
Mfr report #	2001023207-1
UF/Dist report #	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 2

B. Adverse event or product problem

7. Other relevant history, including preexisting medical conditions
blood clot behind her left knee about 16 years ago.

DSS

OCT 11 2001

Individual Safety Report



3809723-6-00-01

Approved by FDA on 10/20/93

Triage unit sequence # 153704

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient Information

1. Patient Identifier: [redacted] 2. DOB: [redacted] 3. Sex: MALE 4. Weight: 102.8 kg
AGE: 67 yrs

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 prevent impairment/damage
Initial or prolonged [] other

3. Date of event: 07/02/01 4. Date of this report: 07/06/01

5. Describe event or problem: gi bleed

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

EBD by descendant when 7/7/01 # pylori (-)

7. Other relevant History, including preexisting medical conditions

DM, peripheral neuropathy, MTN, hyperlipidemia, hypothyroidism, CAD, peripheral vascular disease, colostomy

C. Suspect Medication(s)

1. Name #1: IBUPROFEN

aspirin

2. Dose, frequency & route used

#1: *600mg qid 8am*

3. Therapy dates

#1: *> 1yr PTA > 1yr PTA*

4. Diagnosis for use (indication)

#1: *pain CAD*

5. Event abated after use stopped or dose reduced?

#1: [N/A] *yes yes*

6. Lot # (if known)

#1:

7. Exp. date

#1:

8. Event reappeared after reintroduction

#1: [] *N/A*

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment):
DILTIAZEM (TIAZAC) 360MG SA CAP
FUROSEMIDE 40MG TAB
NORTRIPTYLINE HCL 25MG CAP
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]
VA MEDICAL CENTER 135 E. 38TH STREET
ERIE, PENNSYLVANIA 16504-1596 [redacted]

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

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

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.

CTV153704

OCT 16 2001

DSS

Individual Safety Report



3809723-6-00-02

P 2-62
153704

ATTACHMENT PAGE

SUSPECT MEDICATION: IBUPROFEN

DATE OF EVENT: 7/2/01

PATIENT ID: [REDACTED]

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

TEST: HGB RESULTS: L 9.0 g/dl H:18/L:14 COLLECTION DATE: 7/5/01@14:00
 TEST: CREATININE RESULTS: H 2.0 mg/dl H:1.2/L:.7 COLLECTION DATE: 7/5/01@14:00
 TEST: HGB RESULTS: L 10.4 g/dl H:18/L:14 COLLECTION DATE: 7/2/01@11:29
 TEST: CREATININE RESULTS: H 1.7 mg/dl H:1.2/L:.7 COLLECTION DATE: 7/2/01@11:29
 TEST: CREATININE RESULTS: H 1.5 mg/dl H:1.2/L:.7 COLLECTION DATE: 6/12/01@10:43
 TEST: HGB RESULTS: L 13.2 g/dl H:18/L:14 COLLECTION DATE: 6/12/01@10:43

Section C. Part 10. Concomitant Drugs Continued

ACETAMINOPHEN 500MG TAB
 CASANTHRANOL 30/DOCUSATE NA 100MG CAP
 FERROUS SULFATE 325MG TAB
 LEVOTHYROXINE NA (SYNTHROID) 0.125MG TAB
 LISINAPRIL 20MG TAB
 SIMVASTATIN 40MG TAB
 CAPSAICIN 0.025% CREAM
 MULTIVITAMIN/MINERALS THERAPEUT CAP/TAB
 ISOSORBIDE DINITRATE 40MG SA TAB
 ASPIRIN 81MG EC TAB
 TRIAMCINOLONE ACETONIDE 0.1% CREAM 15GM
 CLOTRIMAZOLE 1% TOP CREAM
 DEXAMETHASONE 0.1%/NEO/POLYMX OPH OINT
 INSULIN NOVOLIN 70/30 (NPH/REG) INJ NOVO

1kg	7/6	9.2	
	7/7	9.8	19.0
	7/8	9.5	8.6 transfused
	7/9	10.4	unit

7/8 bp 85/54

Cc 7/8 1.7

BUN 42

153704

OCT 16 2001

Individual Safety Report



3809725-X-00-01

MEDwatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Approved by FDA on 10/20/93

Triage unit sequence # 153705

Page 1 of 2

A. Patient Information

1. Patient Identifier: [redacted] 2. DOB: [redacted] 3. Sex: MALE 4. Weight: 118.2 kg
AGE: 60 yrs

B. Adverse Event or Product Problem

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

3. Date of event: 07/06/01 4. Date of this report: 07/10/01

5. Describe event or problem: gi bleed - duodenal ulcer + gastritis

C. Suspect Medication(s)

1. Name #1: IBUPROFEN

Aspirin

2. Dose, frequency & route used #1: 325mg po qd 3. Therapy dates #1: 6/01 - 8/01 P/A

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

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

9. (Not applicable to adverse drug event reports)

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

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10. Concomitant medical products/therapy dates (exclude treatment): METOPROLOL TARTRATE 50MG TAB, ASPIRIN 325MG EC TAB, LOVASTATIN 40MG TAB. PLEASE SEE ATTACHED

7. Other relevant history, including preexisting medical conditions: S/P CABG-5 vessel in 6/01, htn, obesity, MI, hyperlipidemia, DM, pacemaker

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] VA MEDICAL CENTER 135 E. 38TH STREET ERIE, PENNSYLVANIA 16504-1596 [redacted]

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

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

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.

CTU 153705

OCT 16 2001

Individual Safety Report



3809725-X-00-02

153705

ATTACHMENT PAGE

SUSPECT MEDICATION: IBUPROFEN

DATE OF EVENT: 7/6/01

PATIENT ID: [REDACTED]

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

TEST: HPYLORI RESULTS: NEGATIVE H:neg/L: COLLECTION DATE: 7/10/01@05:30
 TEST: HGB RESULTS: L 9.3 g/dl H:18/L:14 COLLECTION DATE: 7/10/01@05:30
 TEST: HGB RESULTS: L 8.8 g/dl H:18/L:14 COLLECTION DATE: 7/9/01@05:30
 TEST: HGB RESULTS: L 9.2 g/dl H:18/L:14 COLLECTION DATE: 7/8/01@15:00
 TEST: HGB RESULTS: L 9.1 g/dl H:18/L:14 COLLECTION DATE: 7/8/01@05:30
 TEST: HGB RESULTS: L 8.2 g/dl H:18/L:14 COLLECTION DATE: 7/7/01@15:00
 TEST: HGB RESULTS: L* 7.3 g/dl H:18/L:14 COLLECTION DATE: 7/7/01@05:30
 TEST: HGB RESULTS: L* 7.4 g/dl H:18/L:14 COLLECTION DATE: 7/6/01@20:41
 TEST: HGB RESULTS: L* 7.9 g/dl H:18/L:14 COLLECTION DATE: 7/6/01@17:14
 TEST: HGB RESULTS: 17.9 g/dl H:18/L:14 COLLECTION DATE: 6/5/01@09:11

Section C. Part 10. Concomitant Drugs Continued

VALSARTAN 80MG CAP
 PROPOXYPHENE N 100/APAP 650MG TAB
 HCTZ 50/TRIAMTERENE 75MG TAB
 VALSARTAN CAP,ORAL
 LOVASTATIN TAB
 METOPROLOL TARTRATE TAB
 FOLIC ACID TAB
 HYDROCHLOROTHIAZIDE TAB

07/06/01-08/05/01
 07/06/01-08/05/01
 07/06/01-08/05/01
 07/06/01-08/05/01
 07/06/01-07/07/01

153705

DSS
OCT 16 2001

Individual Safety Report



3809729-7-00-01

Approved by FDA on 10/20/93

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 153707

Page 1 of 1

A. Patient Information

1. Patient Identifier [redacted] 2. DOB: [redacted] 3. Sex: MALE 4. Weight: 75.3 kg
AGE: 47 yrs

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 prevent impairment/damage
initial or prolonged [] other

3. Date of event: 09/19/01 4. Date of this report: 09/21/01

5. Describe event or problem: gi bleed

Endoscopy - transfused.

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MEDWATCH CTU

6. Relevant test/laboratory data, if any: PLEASE SEE ATTACHED

C. Suspect Medication(s)

1. Name
#1: ASPIRIN
#2: NAPROXEN 500MG TAB

2. Dose, frequency & route used
#1: 325 mg qd
#2: bid
3. Therapy dates
#1: before 9/01
#2: before 6/2000 - 9/01

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

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

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
MULTIVITAMIN/MINERALS THERAPEUT CAP/TAB
CLONAZEPAM 0.5MG TAB
NEFAZODONE 100MG TAB
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]
VA MEDICAL CENTER 135 E. 38TH STREET
ERIE, PENNSYLVANIA 16504-1596 [redacted]

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

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

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.

CTU 153707

SSS

OCT 16 2001

Individual Safety Report



3809729-7-00-02

153707

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: ASPIRIN

DATE OF EVENT: 9/19/01

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

TEST: HGB RESULTS: L 12.3 g/dl H:18/L:14 COLLECTION DATE: 9/21/01@05:30
 TEST: HGB RESULTS: L 11.9 g/dl H:18/L:14 COLLECTION DATE: 9/20/01@18:00
 TEST: HGB RESULTS: L 11.8 g/dl H:18/L:14 COLLECTION DATE: 9/20/01@05:30
 TEST: HGB RESULTS: L 11.8 g/dl H:18/L:14 COLLECTION DATE: 9/19/01@20:30
 TEST: HGB RESULTS: L 8.9 g/dl H:18/L:14 COLLECTION DATE: 9/19/01@05:30
 TEST: HGB RESULTS: L 9.0 g/dl H:18/L:14 COLLECTION DATE: 9/18/01@22:30
 TEST: HGB RESULTS: L 10 g/dl H:18/L:14 COLLECTION DATE: 9/18/01@15:38

Section C. Part 10. Concomitant Drugs Continued

OXYCODONE HCL 5MG TAB
 GABAPENTIN 100MG CAP
 SILDENAFIL CITRATE 50MG TAB
 LANSOPRAZOLE 15MG SA CAP

153707

DSS
OCT 1 5 2001



Kos Pharmaceuticals, Inc.

Approved by FDA on 3-22-94

Domain Facsimile
Mfr report # 11080
JF/Dial report #
FDA Use Only

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 4

A. Patient information

1. Patient Identifier UNK in confidence	2. Age at time of event: 75 yrs or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> 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)

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

3. Date of event (mortality) 08/05/2001

4. Date of this report (mortality) 10/16/2001

5. Describe event or problem

This physician reported via a Kos representative, that a patient with a history of non-insulin diabetes was hospitalized for pancreatitis while on Niaspan.

The physician was contacted and reported that the patient was on 500 mg Niaspan for five days at the time of hospitalization. He reported that Lipitor was discontinued a couple of months prior to the initiation of Niaspan, therefore, combination therapy was not a concern. He also indicated that the patient was diagnosed with a renal mass prior to Niaspan therapy.

The physician felt that renal mass may have precipitated the patient's current *

6. Relevant tests/laboratory data, including dates

Follow-up information:

5 Aug 01:
Blood pressure = 100/58 mm/Hg
Pulse = 73 bpm
Lipase = 790 IU/L *

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

Hypertension; Non-insulin dependent diabetes mellitus; Peripheral vascular disease; No history of alcoholism or pancreatitis; Experienced muscle pain and other medical problems in the past with Baycol, Zocor and Lipitor; Renal mass; 1993 fem-pop-surgery; *

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 NIASPAN	
#2 ASPIRIN	
2. Dose, frequency & route used	
#1 500 MG QHS PO	
#2 UNK	
3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1 UNK to 05-AUG-2001	
#2 UNK, not continuing	
4. Diagnosis for use (indication)	
#1 ELEVATED TRIGLYCERIDES	
#2 CORONARY ARTERY DISEASE	
5. Event abated after use stopped or dose reduced	
#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	
#1 UNK	
#2 UNK	
7. Exp. date (if known)	
#1 Unknown	
#2 Unknown	
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
#1 NA	#2 UNK

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

Name: MONOPRIL Dates: UNK, continuing Duration: a few years

Name: NORVASC Dates: UNK, continuing Duration: a few *

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)	2. Phone number
Kos Pharmaceuticals, Inc. 14875 NW 77th Ave. Miami Lakes, FL 33014	(305) 512-7000
4. Date received by manufacturer (mortality)	5. (A)NDA # 20-381
09/17/2001	IND # _____
6. If IND, protocol #	PLA # _____
	pre-1938 <input type="checkbox"/> yes
7. Type of report (check all that apply)	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1	
9. Mfr. report number	8. Adverse event term(s)
11080	PANCREATITIS, STOMACH ULCER, MELENA, NEOPLASM, UREMIA, ALBUMINURIA, HYPOTENSION

3. Report source (check all that apply)

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

OCT 18 2001

E. Initial reporter

1. Name, address & phone #		OCT 17 2001
Dr. [redacted] AVE SUITE [redacted] USA Phone: [redacted]		
2. Health professional? <input checked="" type="checkbox"/> yes <input 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



Domain Facsimile of FDA Form 3500A

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



3810656-X-00-02

Kos Pharmaceuticals, Inc.

MED WATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 2 of 4
	UNK	11080	

B.5. Describe event or problem

[continuation:] condition. He stated that the patient will undergo further evaluation for the renal mass. During hospitalization, the physician reported that the patient was discontinued from Niaspan therapy. He further reported that the patient the patient was discharged home. In the opinion of the physician, Niaspan was not the cause of the patient's pancreatitis.

Follow-up information:

Medical records were received on 02 Oct 01 indicating that prior to initiating Niaspan, the patient had been on Baycol 0.4 mg. During Baycol therapy, the patient experienced increased fatigue, nausea, sleepiness and a drugged sensation. The patient was discontinued from Baycol due to the symptoms, and Niaspan therapy was initiated. Medical records indicated that Niaspan was initiated approximately two weeks after discontinuing Baycol therapy. At the time of hospitalization, the patient had been on 500 mg Niaspan for approximately one week.

At the time of the event, the patient presented to the emergency room with a two day history of right upper quadrant pain that radiated to his back. The pain was described as a hot poker sticking through the patient's abdomen and was associated with nausea. It was noted that the pain was constant, and was experienced two hours after dosing with Niaspan. The pain improved after the patient took narcotic medication on his own accord. At the emergency room, further evaluation revealed a heme positive stool, and the patient was admitted.

During the course of hospitalization the patient remained stable, however experienced sinus tachycardia for the first few days that was felt to be due to the stress of his illness. An endoscopy revealed gastric ulcerations. Aspirin therapy was discontinued, and he was treated with Protonix IV for gastric ulcerations and a heme positive stool. Niaspan therapy was also discontinued. An abdominal ultrasound revealed multiple bilateral renal masses that may have represented cysts, and a solid left mid kidney mass in the pancreatic area that was suggestive for pancreatitis with a questionable hypoechoic region in the head of the pancreas. An magnetic resonance imaging of the abdomen was ordered, however due to unclear film, the patient underwent a computerized tomography scan. Results revealed similar findings compared to the abdominal ultrasound. Results also revealed a solid left 2 cm renal mass, noted as possible renal carcinoma. Initially the patient's blood pressure was low, but once the patient was rehydrated with intravenous fluid, and consumed food, his blood pressure increased. His blood pressure remained stable and he was restarted on his antihypertensive medications. The patient was diagnosed with pancreatitis possibly secondary to Niaspan, gastric ulcerations, heme positive stool, and a solid renal mass. The patient additionally experienced mild dehydration, renal azotemia and proteinuria. After 6 days of hospitalization the patient was discharged home.

Records indicated that the patient was instructed to avoid Niacin and Niaspan, which could be associated with his pancreatitis. Further recommendation included a repeat imaging evaluation to rule out malignancy.

DSS

OCT 18 2001

OCT 17 2001



Kos Pharmaceuticals, Inc.

MED WATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 3 of 4
	UNK	11080	

B.6. Relevant tests/laboratory data including dates

[continuation:] WBC = 11.9
 LFT = normal
 Creatinine = 1.5
 Electrocardiogram = sinus tachycardia, low voltage
 Duodenum biopsies = non-specific
 Gastric biopsy = minimal chronic gastritis, negative for Helicobacter
 Hemoglobin = 14.9
 Hematocrit = 45
 Glucose = 140
 BUN = 21
 Heme positive stool
 Abdominal ultrasound = mutiple bilateral renal masses; solid-appearing left mid-kidney mass

8 Aug 01:
 Creatinine = 1.3
 WBC = 8.6
 Amylase = 218 IU/L
 Lipase = 442 IU/L

10 Aug 01:
 Amylase = 265
 Lipase = 596
 Albumin = +2

Unknown date:
 Endoscopy = gastric ulcerations
 CT Scan = 2 cm left renal mass (possible renal carcinoma)

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

[continuation:] 1997 myocardial infarction(x 2 stents); Benign prostatic hypertrohy s/p surgery; Swelling of the saliva glands that resulted in saliva gland stone surgery; Cataract surgery; Right and left total knee replacements; Allergic to Floxin (caused Achilles tendon problems); Eypercholesterolemia; Coronary artery disease; Possible borderline eye pressures; Heart problems in 1993; Enlarged heart; Colonoscopy ten years ago

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Kos Pharmaceuticals, Inc.

MED WATCH	A.1. Patient Identifier UNK	G.9. Mfr. report number 11080	Page 4 of 4
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C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] years

- Name: GLYBURIDE Dates: UNK, continuing
- Name: TOPROL XL Dates: UNK, continuing
- Name: GLUCOPHAGE Dates: UNK to 10-AUG-2001
- Name: ULTRAM Dates: UNK, not continuing

E.3. Occupation

FAMILY PRACTITIONER

DSS
OCT 18 2001

OCT 17 2001

Individual Safety Report



3811162-9-00-01

Voluntary reporting
by professionals of adverse
events and product problems

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

FDA Use Only H Pad

Trace unit:
sequence # 154055

Page ___ of ___

A. Patient information

1. Patient Identifier: [Redacted] In confidence

2. Age at time of event: 62
or Date of birth: _____

3. Sex: female male

4. Weight: _____ lbs or 89 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 (immediate)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (month/year): 12-18-00

4. Date of this report (month/year): 8/10/01

5. Describe event or problem:
 WEAKNESS ON STANDING
 weakness on standing
 dehydration
 GI ulcer noted
 tx w rehydration - 2 units
 PRBC - DIC YIBU E Bufferin
 instructed to stop drinking +
 1bu + Bufferin

6. Relevant tests/laboratory data, including dates:
 admission - Bp = 96/60 HR = 140
 Hb = 7.7 HCT = 22.6
 at discharge Hb = 9.3 HCT = 27.2
 normal ⊕ stools

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 Gastric ulcer - DM2 - HTN
 DJD - Arthritis
 alcoholism
 CTX 154055

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known):
 #1 YIBU E Bufferin
 #2 ERG 1000

2. Dose, frequency & route used:
 #1 po
 #2 _____

3. Therapy dates (if unknown, give duration) (month or best estimate):
 #1 ?
 #2 _____

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

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

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

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

8. Event recurred 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: MEDWATCH CTU

2. Type of device: _____

3. Manufacturer name & address: _____

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

5. Expiration date (month/year): _____

6. model #: MEDWATCH CTU

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):
 DSS
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E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [Redacted]

2. Health professional? yes no

3. Occupation: PharmD

4. Also reported to:
 manufacturer
 user facility
 distributor

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



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

or FAX to:
1-800-FDA-0178

Individual Safety Report



3811259-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
health professionals of adverse
events and product problems

Page 1 of 1

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

FDA Use Only H Pad

Triage unit sequence # 154018

A. Patient information

1. Patient Identifier: 2373
In confidence

2. Age at time of event: 52 YO
or Date of birth:

3. Sex: female male

4. Weight: 114 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 (no day/yr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event (mo/day/yr): 04/11/01

4. Date of this report (mo/day/yr): 04/23/01

5. Describe event or problem:
 Pt. adm to hosp for surgical repair of perforated duodenal ulcer. Prior to admission, patient was taking Vioxx 50mg once daily. Also, pt. was taken aspirin prior to adm (unknown strength and frequency).

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.):
 H/o metastatic breast cancer
 Other meds taken @ home:
 D-N-KC, KDur, Atenolol, Xeloda, Compazine, Lasix, Ativan, Phenergan, Bactrim DS, Isosorbide mononitrate, nitroglycerin PRN, & aspirin

C. Suspect medication(s)

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

2. Dose, frequency & route used:
 #1 50mg once daily
 #2 ?

3. Therapy dates (if unknown, give start/stop dates):
 #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 (include treatment of event):

D. Suspect medical device

1. Brand name:

2. Type of device:

3. Manufacturer name & address:
 RECEIVED
 OCT 18 2001
 MEDWATCH CTU

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

5. Expiration date:

6. model #, catalog #, serial #, lot #, other #:

7. If implanted, give date:

8. If explanted, give date:

9. Device available for evaluation? (Do not send to manufacturer or returned to manufacturer or DSS)
 yes no returned to manufacturer or DSS

10. Concomitant medical products and therapy dates (include treatment of event):
 OCT 19 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:
 Pharm D.
 Medical Center
 Avenue

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

FDA Form 3500 (6/93)

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

Individual Safety Report



3811270-2-00-01

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
with professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **Fax to Ann Greenwald**
153998

A. Patient information			
1. Patient identifier [redacted]	2. Age at time of event: 66 Years or Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
B. Adverse event or product problem			
1. <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 05/04/2001 (mm/dd/yyyy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____			
3. Date of event 05/03/2001 (mm/dd/yyyy)		4. Date of this report 10/17/2001 (mm/dd/yyyy)	
5. Describe event or problem The patient was admitted to the hospital on 5/3/01 with chest pain. She was found to be hypotensive with a BP of 90/40. She was given IV fluid boluses. An NG tube was placed and bright red blood was aspirated indicating a GI bleed. The patient was also guaiac positive. The patient's medications on admission included Plavix 75 mg qd, EC ASA 160 mg, and warfarin 2.5 mg alternating with 5 mg. Her INR on admission was 5. The patient was treated with FFP. However, she developed acute pulmonary edema and was treated with furosemide. She was transferred to CCU but developed an elevated ST segment, cardiogenic shock, respiratory depression and expired.			
6. Relevant tests/laboratory data, including dates 5/3 INR-5.0 H/H 8/24.2; 7.2/22			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) PMH: Afib since 1991, CHF, DM, HTN, 3/27 Hematochezia, hematemesis 3/30 Cardiac cath - PTCA with stent S/P MI			

CTV 153998
MEDWATCH

C. Suspect medication(s)			
1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)		1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 Warfarin / /		#1 Warfarin / /	
#2 Plavix/ASA / /		#2 Plavix/ASA / /	
2. Dose/Frequency/Route used		3. Therapy dates (if unknown, give duration)	
#1 5 mg, /QD, /Oral		#1 From - To (or best estimate)	
#2 75 mg/16 /QD /Oral		#2 03/30/2001 - 05/03/2001	
4. Diagnosis for use (separate indications with commas)		5. Event abated after use stopped or dose reduced	
#1 Afib		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 PTCA with stent		#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	
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 (exclude treatment of event) Digoxin 0.25 mg QD Isosorbide Glyburide 5 mg bid ASA 160 Lipitor 40 mg QD Lasix 80 mg D Protonix 40 mg QD Metoprolol			
D. Suspect medical device			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of device	
RECEIVED OCT 18 2001		<input type="checkbox"/> health professional	
		<input type="checkbox"/> lay user/patient	
6. model # MEDWATCH CTU		<input type="checkbox"/> other: _____	
7. Expiration date (mm/dd/yyyy)		5. Expiration date (mm/dd/yyyy)	
8. If implanted, give date (mm/dd/yyyy)		7. If implanted, give date (mm/dd/yyyy)	
8. If explanted, give date (mm/dd/yyyy)		8. If explanted, give date (mm/dd/yyyy)	
9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer (mm/dd/yyyy)			
10. Concomitant medical products and therapy dates (exclude treatment of event) DSS OCT 19 2001			

E. Reporter (see confidentiality section on back)			
1. Name		phone #	
[redacted]		[redacted]	
[redacted] St.		[redacted]	
United States			
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 checked="" type="checkbox"/>	

FDA 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.

RECEIVED



3811270-2-00-02

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5

153998

C10. Concomitant medical products and therapy dates continued

25 mg bid Glucophage 500 mg bid Ranitidine 150 mg bid SR KCL 10 mEq tid

D10. Concomitant medical products and therapy dates continued

DSS

OCT 19 2001

153998

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.

Individual Safety Report



3811291-X-00-01

LUNTARY reporting
professionals of adverse
and product problems

Form Approved: OMB No. 0916-0291 Expires 12/31/04
See OMB statement on reverse

FDA Use Only

Trace unit sequence # 154082

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient Identifier: [Redacted] In confidence

2. Age at time of event: 79 or Date of birth: [Redacted]

3. Sex: female male

4. Weight: 75.9 lbs or 34.4 kgs

B. Adverse event or product problem

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

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

3. Date of event: 6/15/01

4. Date of this report: 10/18/01

5. Describe event or problem:
 79yo female receiving aspirin 325mg + rofecoxib 25mg qd. developed GI bleed requiring transfusion of 4 units PRBC's. Pt had one week history of substernal burning. Had been having lethargy, weakness, fatigue, tarry stools x 1 month.

6. Relevant tests/laboratory data, including dates:
 Hgb = 7.7
 Hct = 12.9

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known):
 #1 Vioxx 25mg
 #2 Aspirin 325mg

2. Dose, frequency & route used:
 #1 25mg qd
 #2 325mg qd

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

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

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

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

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

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

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

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

D. Suspect medical device

1. Brand name: _____

2. Type of device: _____

3. Manufacturer name & address: _____

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

5. Expiration date (mo/day/yr): _____

6. model #: _____
 catalog #: MEDWATCH CTU
 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):
 DSS
 OCT 19 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:
 [Redacted] Pharmacy St.

2. Health professional? yes no

3. Occupation: Pharmacist

4. Also reported to:
 manufacturer
 user facility
 distributor

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

CV 154082



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

or FAX to:
1-800-FDA-9178
OCT 19 2001



3913334-6-88-01

Page of

CDER 154225

II. Patient information

Patient identifier 5365	2. Age at time of event: 42	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence	Date of birth:		

III. Adverse event or product problem

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

Outcomes attributed to adverse event (check all that apply)

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

Date of event (month/year): 8/28/01

4. Date of this report (month/year): 8/28/01

Describe event or problem

At 2 AM and known non compliance with warfarin on warfarin since hospital d/c 8/1/01. At was no show to AC Clinic. Presents with coffee ground emesis x1, dark stool x2 days and diffuse leg bruising at injection sites. Met 15. Pt admitted to MICU and received 10mg vitamin K, 3 units FFP, 8 units PRBCs, ranitidine. Seen by GT with negative ECG and NG lavage

Relevant tests/laboratory data, including dates

and orthopedics who ruled out compartment syndrome.

Met 40 -> 15

INR 7.25 PT 730

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

pneumothorax, AMR, IVDA, COPD, aortic atherosclerosis

severe probable

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)
#1 warfarin WARFARIN	#1 7.5mg QD	#1 8/4 - present
#2 aspirin ASPIRIN	#2 650mg QD	#2 x1 week
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 AVR	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 leg clamps	#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 (month/year)
RECEIVED OCT 23 2001	7. If implanted, give date (month/year)
6. model #	8. If explanted, give date (month/year)
catalog # MEDWATCH CTU	
serial #	
lot #	
other #	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (month/year)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)

1. Name, address & phone #	2. Health professional?	3. Occupation	4. Also reported to:
[redacted] Pharm D St	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Clinical Pharmacist	<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 5500 Fishers Lane 1-800-FDA-0178

or FAX to: 1-800-FDA-0178

301-552-9757

Form 3500 (3/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV154225 OCT 22 2001

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Individual Safety Report



3813379-6-00-01

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

NO. 015 0021

154325

FDA Use Only: Please check appropriate box. See back cover of form.

FD-1089 (Rev. 10/97) **IMAGE** [REDACTED]

ADVERSE EVENT REPORTING PROGRAM

A Patient Information

1. Patient identifier: [REDACTED]

2. Age at time of event: 73
or Date of birth: [REDACTED]

3. Sex: male female

4. Weight: [REDACTED] lbs or [REDACTED] kg

B Adverse event or product problem

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

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): 10/21/01

4. Date of this report (month/year): 10/23/01

5. Describe event or problem

GI Bleed from diverticulitis while taking Vicor 25mg
 Pt also on: ASA 325 mg
 Coumadin
 Elavil 25mg
 Nexavar 500mg

B. Relevant test/laboratory data, including dates

Amenorrhea 20 bleed - HT, TICS.

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

DME (2)

C Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
 #1 Vicor
 #2 ASA

2. Dose, frequency & route used
 #1 25mg po qd
 #2 [REDACTED]

3. Therapy dates (if unknown, give duration)
 #1 [REDACTED]
 #2 [REDACTED]

4. Diagnosis for use (indication)
 #1 Pain @ shoulder
 #2 [REDACTED]

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

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

7. Exp. date (if known)
 #1 [REDACTED]
 #2 [REDACTED]

8. Lot # (if known)
 #1 [REDACTED]
 #2 [REDACTED]

9. NDC # (for product problems only)
 #1 [REDACTED]
 #2 [REDACTED]

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

D Suspect medical device

1. Brand name: [REDACTED]

2. Type of device: [REDACTED]

3. Manufacturer name & address: [REDACTED]

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

5. Expiration date (if any): [REDACTED]

6. Model # [REDACTED]

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

8. If implanted, give date (month/year): [REDACTED]

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

10. Concomitant medical products and therapy dates (exclude treatment of event)
 DSS
 OCT 24 2001

E Reporter

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

2. Health professional? yes no

3. Occupation: MD

4. Also reported to:
 manufacturer
 user (facility)
 distributor

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

PLEASE TYPE OR USE BLACK INK

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9757
 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.

OCT 24 2001



VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0281 Expires 12/31/04
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

154453

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page _____ of _____

A. Patient information			
1. Patient identifier [Redacted]	2. Age at time of event: 39 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or 111.6 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 (mortality)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____		<input type="checkbox"/> other: _____	
3. Date of event (m/d/yyyy): 6/2/01	4. Date of this report (m/d/yyyy): 10/25/01		
5. Describe event or problem GI bleed d/t use of rofecoxib or aspirin			
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 Rofecoxib		#2 Aspirin	
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 osteoarthritis		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 stroke prevention		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
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			
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	
RECEIVED		<input type="checkbox"/> health professional	
		<input type="checkbox"/> lay user/patient	
OCT 26 2001		<input type="checkbox"/> other: _____	
		5. Expiration date (m/d/yyyy)	
6. model #		7. If implanted, give date (m/d/yyyy)	
catalog # MEDWATCH CTU		8. If explanted, give date (m/d/yyyy)	
serial #			
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____			
10. Concomitant medical products and therapy dates (exclude treatment of event): OCT 26 2001			

E. Reporter (see confidentiality section on back)			
1. Name, address & phone # [Redacted]			
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 checked="" type="checkbox"/>			



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



155023

1. PATIENT IDENTIFIER: 8393
 2. AGE at time of event: 80
 3. Sex: female male
 4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

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

3. Date of event (m/d/yy): 9/4/01
 4. Date of this report (m/d/yy): 10/10/01

Describe event or problem
 At admitted for hematochezia.
 NG lavage @. EGD: duodenal ^{water probe} retraction
 AVM, gastric ulcer. Colonoscopy.
 Abdominal CT: ischemic colitis
 Admitted to ICU, 6 units FFP,
 celecoxib, aspirin held.

Relevant tests/laboratory data, including dates
 Hct 45 → 32
 INR 2.04

Other relevant history, including preexisting medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 duodenal AVM, Barrett's esophagus,
 CHF, PUD, AFib, HTN, CRI
 severe probable

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20857
 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.

CTV155023
 NOV 06 2001
 RECEIVED

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 Aspirin
 #2 warfarin
 2. Dose, frequency & route used
 #1 81mg QD
 #2 3mg QD
 3. Therapy dates (if unknown, give duration)
 #1
 #2
 4. Diagnosis for use (indication)
 #1 CAD prophylaxis
 #2 CAD prophylaxis
 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 CVA
 7. Exp. date (if known)
 #1
 #2
 8. 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
 RECEIVED
 NOV 06 2001
 MEDWATCH CTU
 4. Operator of device
 health professional
 lay user/patient
 other
 5. Expiration date (m/d/yy)
 6. model #
 catalog #
 serial #
 lot #
 other #
 7. If implanted, give date (m/d/yy)
 8. If explanted, give date (m/d/yy)
 9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on (m/d/yy)
 10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
 Pharm D
 St
 2. Health professional? yes no
 3. Occupation
 Clinical 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.

NOV 06 2001

Individual Safety Report

410 605 7852

T-612 P.011/013 F-535



155014

A. Patient Information

1. Patient Identifier: 3738
 2. Age at time of event: 59
 3. Sex: female male
 4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

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

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

Date of event: 10/16/01
 Date of this report: 10/17/01

Describe event or problem:
 Pt initially admitted to the floor for anasarca. There he had a massive stool and ⊕ NG lavage which cleared p 2 liters. Pt transferred to MICU. EGD revealed hemorrhage in the stomach, but no source of the bleed. Pt received 6 units PRBCs, reduprags and aspirin held.

Relevant tests/laboratory data, including dates:
 Hct 29 → 21.5

Other relevant history, including preexisting medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 CAD, CHF, CPE, DM, HTN, anemia

Severe probable

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.

CTV155014 NOV 06 2001

C. Suspect medication(s)

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

2. Dose, frequency & route used:
 #1 325mg QD
 #2 _____

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

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

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

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

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

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

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

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

D. Suspect medical device

1. Brand name: _____

2. Type of device: _____

3. Manufacturer name & address: _____

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

5. Expiration date (mo/day/yr): _____

6. Model #: NOV 06 2001

7. If implanted, give date (m-/d/yy/yr): _____

8. If explanted, give date (m-/d/yy/yr): _____

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on _____ (m-/d/yy/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] St
 [Redacted]

2. Health professional? yes no

3. Occupation: Clinical 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.

NOV 06 2001

Individual Safety Report



3823024-1-00-01

VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/04

FDA Use Only X Fed

Trips unit response #

155353

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier: 1303
in confidence

2. Age at time of event: 72
or Date of birth:

3. Sex: female male

4. Weight: ___ lbs or 62 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 (mandatory)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (mandatory): 9/5/01

4. Date of this report (mandatory): 11/8/01

5. Describe event or problem:
 GI bleed/Gastritis 2° to high dose ASA therapy taking 650mg/d for retinal artery occlusion

6. Relevant tests/laboratory data, including dates

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

C. Suspect medication(s)

1. Name (give labeled strength & ml/labeler, if known)
 #1: Aspirin
 #2: _____

2. Dose, frequency & route used
 #1: 650mg QD
 #2: _____

3. Therapy dates (if unknown, give duration; none for best estimate)
 #1: ?
 #2: _____

4. Diagnosis for use (indication)
 #1: Retinal art occlusion
 #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 (mandatory)

6. model # NOV 09 2001

7. If implanted, give date (mandatory)

8. If explanted, give date (mandatory)

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

10. Concomitant medical products and therapy dates (exclude treatment of event)
 NOV 12 2001

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 OF FAX to: 1-800-FDA-0178

NOV 09 2001 RECEIVED

CTU 155353

Individual Safety Report



3824043-1-00-01

MEDWATCH

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

Form Approved: OMB No. 0910-0291

Mfr report # 155474
 UF/Dist report # FOA 2015632-001-003
 FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 7

A. PATIENT INFORMATION

1. Patient identifier [redacted] 2. Age at event 61 Years or DOB: [redacted] 3. Sex [] female [X] male 4. Weight 86 lbs or 86 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [] Product problem

2. Outcomes attrib. to event [] death (mo/day/yy) [] life-threatening [X] hospitalization - initial or prolonged [] disability [] congen anomaly [] required intervention to prevent perm impair/damage [] other:

3. Date of event 09/19/2001 4. Date of this Rept 11/05/2001

5. Describe event or problem
 Presented to VA ER with c/o N/V, abdominal pain, and melena x 2 days. He has a h/o GI bleeds with last one 15 years ago. He was positive for Helicobacter pylori and diagnosed with a duodenal ulcer. His treatment included metronidazole, clarithromycin and rabeprazole. Due to H. Pylori positive status, the exact association with NSAIDs is unknown, but likely contributory. His NSAIDs were DC on discharge from hospital.

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

7. Other relevant history, including preexist. med. conditions
 HTN, CAD (S/P MI x 4), S/P angioplasty, hyperlipidemia, prostate cancer 2 years ago, anxiety, depression PUD 1978, GI bleed 15 years ago, hiatal hernia and chronic back pain.

CTV 155474

C. SUSPECT MEDICATION(S)

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

2. Dose, frequency & route
 #1 75 mg BID PO
 #2 325 mg QD PO

3. Therapy dates (if unk, give dur)
 #1 05/01/2000 - 09/21/2001
 #2 >4 years

4. Diagnosis for use (indication)
 #1 Chronic back pain
 #2 MI prophylaxis

5. Event abated after use stopped or dose reduced
 #1 [X]yes []no []N/A
 #2 [X]yes []no []N/A

6. Lot # (if known) 7. Exp. Date
 #1 [redacted] #1 [redacted]
 #2 [redacted] #2 [redacted]

9. NDC # for prod problems only
 #1 [redacted]
 #2 [redacted]

8. Event reappeared after reintroduction
 #1 []yes []no [X]N/A
 #2 []yes []no [X]N/A

10. Concomitant medical products and therapy dates
 Acetaminophen, Baclofen, Hydroxyzine, Meclizine, Nitroglycerin SL, Simvastatin, Temazepam, Trazodone, Venlafaxine

D. SUSPECT MEDICAL DEVICE

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of Dev.
 [] Hlth Profes.
 [] lay user/pat.
 [] other:

5. Expiration Date

6. Model# NOV 14 2001
 catalog#
 serial# MEDWATCH CTU
 lot#
 other#

7. If implanted, give date

8. If removed, give date

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

10. Concomitant medical products and therapy dates

E. INITIAL REPORTER

1. Name, address & phone #
 VAMC [redacted]
 2250 Leestown Rd
 Pharmacy Service (CDD-119)
 Lexington, KY 40511
 Phone: [redacted]

DSS
 NOV 14 2001

2. Health professional? [X] yes [] no 3. Occupation Pharmacist 4. Initial reporter also sent report to FDA [] yes [] no [X]unk

MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 Facsimile Form 3500A

Individual Safety Report



3824043-1-00-02

155474

MEDICATION AND DEVICE EXPERIENCE REPORT (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.

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		7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up #	8. Date of this Report
9. Approximate age of device	10. Event problem codes (ref. to coding manual) patient code: [] - [] - [] device code: [] - [] - []		
11. Report sent to FDA? <input type="checkbox"/> yes <input type="checkbox"/> no (mo/day/yr)		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient <input type="checkbox"/> home <input type="checkbox"/> diagnostic facil. <input type="checkbox"/> nursing home <input type="checkbox"/> ambulatory <input type="checkbox"/> outpatient <input type="checkbox"/> surgical facility <input type="checkbox"/> treatment facil. <input type="checkbox"/> other: _____ specify	
13. Report sent to Mfr. <input type="checkbox"/> yes <input type="checkbox"/> no (mo/day/yr)			
14. Manufacturer name/address			

G. ALL MANUFACTURERS

1. Contact office - name/address		2. Phone number	
4. Date Rec'd by Mfr.		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:	
6. If IND, protocol #	5. (A)NDA#		
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input type="checkbox"/> follow-up #	IND#		
9. Mfr. report number	PLA#		
	pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product		
8. Adverse event term(s)			

155474

H. DEVICE MANUFACTURERS ONLY

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guid.) <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"/> eval summ attach <input type="checkbox"/> no (attach page to expl. why not) or provide code:	4. Device manufacture date (mo/yr)	5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no	
6. Evaluation codes (refer to coding manual) method [] - [] - [] - [] results [] - [] - [] - [] conclusions [] - [] - [] - []			
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> pat. monitor. <input type="checkbox"/> relabel. <input type="checkbox"/> modification/adjustment		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 360i(f), list correction/removal rep. num.:			

10. [] Additional mfr. and/or narrative 11. [] Corrected Data

DSS
NOV 14 2001

PATIENT: [REDACTED] Confidential

11/5/01 Page 1 of 2

155474

BLOOD	09/21 2001 07:00	09/20 2001 07:00	09/19 2001 23:56	09/19 2001 15:57	Units	Reference Ranges
WBC	5.6	5.2	6.7	9	K/cmm	5-10
RBC	3.76 L	3.47 L	3.8 L	4.65	M/cmm	4.6-6.2
HGB	11.8 L	11 L	11.8 L	14.3	g/dL	14-18
HCT	33.7 L	31.3 L	34.1 L	41.9 L	%	42-52
MCV	89.7	90.2	89.9	89.9	f1	80-94
MCH	31.4 H	31.5 H	31.2 H	30.8	pg	27-31
MCHC	35	35	34.7	34.3	g/dl	32-36
RDW	13.4	13.7	13.9	13.9		
PLT	219	181	214	307	K/cmm	150-450
MPV	8.2	8	7.7	8	um3	7.4-10.4
LYMPH %				18.9 L	%	24-44
MONO %				6.8 H	%	0-6
GRAN %				73.1	%	42-75
EOS %				1.1	%	0-10
BASO %				.1	%	0-3
LYMPH #				1.7	k/cmm	1.2-3.4
MONO #				.6	k/cmm	.1-.6
GRAN #				6.6 H	k/cmm	1.4-6.5
EOS #				.1	k/cmm	0-.7
BASO #				0	k/cmm	0-.2

---- MICROBIOLOGY ----

Accession: MICRO 01 5522 Received: Sep 20, 2001 13:52
Collection sample: GASTRIC MUCOSAL BIOPSY Collection date: Sep 20, 2001 10:00
Site/Specimen: GASTROINTESTINAL MUCOUS MEMBRANE

Test(s) ordered: H PYLORI SCREEN (UREASE TEST) completed: Sep 20, 2001

* BACTERIOLOGY FINAL REPORT => Sep 20, 2001 TECH CODE: 1158
Bacteriology Remark(s):
UREASE POSITIVE 9-20

Pg. 1

11/05/01 12:03

CONFIDENTIAL NON-ENDOSCOPIC REPORT
NOT INPATIENT DOB: JAN 28, 1940
PROCEDURE DATE/TIME: 09/20/01 09:41
PROCEDURE: ESOPHAGOGASTRODUODENOSCOPY
PROCEDURE SUMMARY:

DIAGNOSIS: INTRODUCTION: MALE PATIENT PRESENTS FOR AN ELECTIVE
INPATIENT EGD. THE INDICATION FOR THE PROCEDURE WAS
GASTROINTESTINAL HEMORRHAGE 578.9.

PRE-EVALUATION: AVAILABLE MEDICAL RECORDS AND HEALTH
SUMMARY WERE REVIEWED. A BRIEF HISTORY (INDICATION) AND
REVIEW OF SYSTEMS OF MAJOR AREAS WERE OBTAINED,
INCLUDING DRUG/LATEX ALLERGIES, SUBSTANCE ABUSE,
ANALGESIA/SEDATION/ANESTHESIA DRUG REACTION,
FOOD/SUBSTANCE/MEDICATIONS TAKEN TODAY, RESPIRATORY,
CARDIOVASCULAR, NEUROLOGIC, AND OTHER DISORDERS.
FINDINGS WERE DOCUMENTED IN ANALGESIA/SEDATION RECORD.
A DIRECTED PHYSICAL EXAM INCLUDING AIRWAY, RESPIRATORY
AND CARDIOVASCULAR AREAS WAS DONE. FINDINGS WERE
DOCUMENTED IN THE SEDATION/ANALGESIA RECORD. THE
PATIENT WAS FOUND TO BE FIT FOR ENDOSCOPY AND
SEDATION/ANALGESIA, WITH POTENTIAL BENEFITS EXCEEDING
RISKS. SEE IV CONSCIOUS SEDATION RECORD FOR FOCUSED
HISTORY/INDICATION, INDICATION FOR PROCEDURE AND
SEDATION/ANAGELSLIA, REVIEW OF SYSTEMS, PREVIOUS

DSS

NOV 14 2001

155474

Individual Safety Report



3824043-1-00-03

155474

SEDATION/ANALGESIA OR ANESTHESIA COMPLICATIONS, ALLERGIES, CURRENT AND TODAY'S MEDICATIONS, PHYSICIAN EXAM OF LUNGS, AIRWAY, HEART, RISK (A.S.A.) AND RISK/BENEFIT ASSESSMENT.

CONSENT: AFTER EXPLANATION OF THE INDICATIONS, POTENTIAL COMPLICATIONS, AND AVAILABLE ALTERNATIVES FOR THE PROCEDURE AND SEDATION/ANALGESIA, AND AFTER GIVING OPPORTUNITY FOR QUESTIONS, INFORMED CONSENT WAS OBTAINED FROM THE PATIENT.

PREPARATION: PULSE, RESPIRATORY RATE, BLOOD PRESSURE, % OXYGEN SATURATION, RESPONSE TO VERBAL COMMANDS, AND VASO-MOTOR SKIN RESPONSE WERE MONITORED. THE PATIENT WAS KEPT NPO AFTER MIDNIGHT. AN INTRAVENOUS LINE WAS INSERTED.

MEDICATIONS: BEFORE AND DURING THE PROCEDURE, MEDICATIONS WERE CAREFULLY TITRATED TO A TOTAL OF: - VERSED 3 MG IV WAS CAREFULLY TITRATED BEFORE DURING THE PROCEDURE TO OBTAIN DESIRED EFFECT - FENTANYL 100 MCG IV BEFORE THE PROCEDURE

PROCEDURE: THE ENDOSCOPE WAS PASSED WITH EASE UNDER DIRECT VISUALIZATION TO THE 2ND PORTION OF THE DUODENUM. RETROFLEXION WAS PERFORMED.

FINDINGS: ESOPHAGUS: THE ESOPHAGUS WAS NORMAL IN APPEARANCE AND THERE WAS NO EVIDENCE OF ESOPHAGITIS, INTRINSIC MASS, EXTRINSIC COMPRESSION, ESOPHAGEAL VARICES, RING, WEB, STRICTURE, MOTOR DISTURBANCE, BARRETT'S EPITHELIUM, DIVERTICULA, OR BLEEDING. STOMACH: THE STOMACH WAS NORMAL IN APPEARANCE AND THERE WAS NO EVIDENCE OF GASTRITIS, GASTRIC ULCERS, GASTRIC VARICES, ANGIODYSPLASTIC LESIONS, HIATAL HERNIA, INTRINSIC MASSES, EXTRINSIC COMPRESSION, GASTRIC POLYPS, OR BLEEDING. THE GASTRIC FOLDS WERE OF NORMAL SIZE, GASTRIC MOTILITY WAS GROSSLY NORMAL, AND NO SURGICAL CHANGES WERE APPRECIATED. PYLORUS: A SINGLE

NON-BLEEDING ULCER WAS SEEN WHICH MEASURED 7 MM. THE ULCER SHOWED NO STIGMATA OF RECENT HEMORRHAGE. DUODENUM: THERE WERE TWO NON-BLEEDING DEEP EDEMATOUS OBSTRUCTING ULCERS IN THE 1ST PORTION OF THE DUODENUM.

COMPLICATIONS: THERE WERE NO COMPLICATIONS ASSOCIATED WITH THE PROCEDURE.

IMPRESSION: 1. THE ESOPHAGUS APPEARED NORMAL. 2. THE STOMACH APPEARED NORMAL. 3. SINGLE NON-BLEEDING ULCER IN THE PYLORUS. 531.3. 4. TWO NON-BLEEDING DEEP EDEMATOUS OBSTRUCTING ULCERS IN THE DUODENUM.

RECOMMENDATION: - FOLLOW-UP ON THE RESULTS OF THE CLO TEST. - FOLLOW RECOMMENDATIONS OF INPATIENT GI CONSULT SERVICE.

Individual Safety Report



3824043-1-00-04

DSS

NOV 14 2001

155474

Individual Safety Report



3824176-X-00-01

MEDWATCH

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

Form Approved: OMB No. 0910-0291

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 6

Mfr report #	155-479
UF/Dist report #	FDA 0156 31-001-037
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient identifier [REDACTED]	2. Age at event 70 Years or DOB:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 76 lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <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	10/24/2001	4. Date of this Rept	11/06/2001
5. Describe event or problem Patient presents to the ER 10/24/01 with h/o falling 4-5 times per day for the past 5 days. He also reported melena over same time period. He has h/o alcoholism and chronic NSAID use. The patient was diagnosed with a GI bleed and was transfused with 4 units of PRBCs. NSAIDs were discontinued and he was instructed to stop consumption of alcohol.			
6. Relevant tests/laboratory data, including dates See attached data.			
7. Other relevant history, including preexist. med. conditions Hiatal hernia, BPH, hypertriglyceridemia, CAD, depression, alcoholism with no h/o DT, HTN, low back pain.			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 Aspirin #2 Diclofenac			
2. Dose, frequency & route #1 325 mg QD PO #2 50 mg BID PO		3. Therapy dates (if unk, give dur) #1 > 1 year #2 01/03/2001 - 10/24/2001	
4. Diagnosis for use (indication) #1 #2 Low back pain		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 #2		7. Exp. Date #1 #2	
9. NDC # for prod problems only #1 #2		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" 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 or			7. If implanted, give date
10. Concomitant medical products and therapy dates			8. If removed, give date

E. INITIAL REPORTER			
1. Name, address & phone # VAMC [REDACTED] 2250 Leestown Rd Pharmacy Service (CDD119) Lexington, KY 40511 USA Phone: [REDACTED]			D55 NOV 14 2001
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Initial reporter also sent report to FDA <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> junk	

CTU/155-479
MED INFO ASSOC Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
Facsimile Form 3500A

Individual Safety Report



3824176-X-00-02

155479

MEDICATION AND DEVICE
EXPERIENCE REPORT
(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.

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		7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up #	
8. Date of this Report			
9. Approximate age of device		10. Event problem codes (ref. to coding manual) patient code [] - [] - [] device code [] - [] - []	
11. Report sent to FDA? <input type="checkbox"/> yes <input type="checkbox"/> no (mo/day/yr)		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient <input type="checkbox"/> home <input type="checkbox"/> diagnostic facil. <input type="checkbox"/> nursing home <input type="checkbox"/> ambulatory <input type="checkbox"/> outpatient <input type="checkbox"/> surgical facility <input type="checkbox"/> treatment facil. <input type="checkbox"/> other: _____ specify	
13. Report sent to Mfr. <input type="checkbox"/> yes <input type="checkbox"/> no (mo/day/yr)			
14. Manufacturer name/address			

G. ALL MANUFACTURERS

1. Contact office - name/address		2. Phone number	
4. Date Rec'd by Mfr.		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 <input type="checkbox"/> professional <input type="checkbox"/> user facility <input type="checkbox"/> company <input type="checkbox"/> representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
6. If IND, protocol #		5. (A)NDA# _____ IND# _____ PLA# _____	
7. Type of report (check all that apply) <input type="checkbox"/> 15-day <input type="checkbox"/> 15-day <input type="checkbox"/> 110-day <input type="checkbox"/> periodic <input type="checkbox"/> Init <input type="checkbox"/> follow-up # _____		8. Adverse event term(s)	
9. Mfr. report number		155479	

H. DEVICE MANUFACTURERS ONLY

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guid.) <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"/> eval summ attach <input type="checkbox"/> no (attach page to expl. why not) or provide code:		4. Device manufacture date (mo/yr)	
		5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no	
6. Evaluation codes (refer to coding manual) method [] - [] - [] - [] results [] - [] - [] - [] conclusions [] - [] - [] - []			
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> pat. monitor. <input type="checkbox"/> relabel. <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 360i(f), list correction/removal rep. num.:	

10. Additional mfr. and/or narrative 11. Corrected Data

DSS
NOV 14 2001

155479

---- CBC & AUTODIFF PROFILE ----

BLOOD	10/27 2001 10:13	10/26 2001 22:37	10/26 2001 17:23	10/26 2001 13:24	10/26 2001 07:00	Units	Reference Ranges
WBC	7.9	9.2	9.8	8.8	8.1	K/cmm	5-10
RBC	3.57 L	3.42 L	3.65 L	3.67 L	3.53 L	M/cmm	4.6-6.2
HGB	11 L	10.7 L	11.4 L	11.3 L	11.1 L	g/dL	14-18
HCT	32 L	31.1 L	33.3 L	33.1 L	31.7 L	%	42-52
MCV	89.5	90.8	91	90.3	89.6	f1	80-94
MCH	30.9	31.3 H	31.2 H	30.8	31.3 H	pg	27-31
MCHC	34.4	34.5	34.2	34.1	34.9	g/dl	32-36
RDW	14.1	14.4	14.3	14.2	14.3		
PLT	366	349	328	375	324	K/cmm	150-450
MPV	7.2 L	7.7	7.6	7.6	7.9	um3	7.4-10.4
LYMPH %						%	24-44
MONO %						%	0-6
GRAN %						%	42-75
EOS %						%	0-10
BASO %						%	0-3
LYMPH #						k/cmm	1.2-3.4
MONO #						k/cmm	.1-.6
GRAN #						k/cmm	1.4-6.5
EOS #						k/cmm	0-.7
BASO #						k/cmm	0-.2

BLOOD	10/25 2001 23:58	10/25 2001 18:30	10/25 2001 07:00	10/25 2001 02:56	10/24 2001 22:24	Units	Reference Ranges
WBC	9.5	10	13.2 H	13.6 H	20.9 H	K/cmm	5-10
RBC	2.47 L	2.85 L	3.07 L	3.38 L	2.73 L	M/cmm	4.6-6.2
HGB	7.8 L	9.3 L	9.8 L	10.7 L	8.8 L	g/dL	14-18
HCT	22.9 L	26.5 L	28.4 L	31.3 L	25.4 L	%	42-52
MCV	92.4	92.8	92.6	92.6	93.1	f1	80-94
MCH	31.7 H	32.4 H	31.9 H	31.8 H	32.2 H	pg	27-31
MCHC	34.3	34.9	34.4	34.3	34.6	g/dl	32-36
RDW	13.2	13.3	13.2	13.5	13.1		
PLT	317	350	352	393	335	K/cmm	150-450
MPV	7.5	7.5	7.9	7.7	7.5	um3	7.4-10.4
LYMPH %						%	24-44
MONO %						%	0-6
GRAN %						%	42-75
EOS %						%	0-10
BASO %						%	0-3
LYMPH #						k/cmm	1.2-3.4
MONO #						k/cmm	.1-.6
GRAN #						k/cmm	1.4-6.5
EOS #						k/cmm	0-.7
BASO #						k/cmm	0-.2

BLOOD	10/24 2001 10:08	Reference Units	Reference Ranges
-------	------------------------	--------------------	---------------------

WBC	11.1 H	K/cmm	5-10
RBC	2.57 L	M/cmm	4.6-6.2
HGB	8.3 L	g/dL	14-18
HCT	23.8 L	%	42-52
MCV	92.4	f1	80-94
MCH	32.3 H	pg	27-31
MCHC	34.9	g/dl	32-36
RDW	12.4		
PLT	371	K/cmm	150-450
MPV	7.4	um3	7.4-10.4
LYMPH %	18.6 L	%	24-44
MONO %	7.3 H	%	0-6
GRAN %	69.7	%	42-75
EOS %	3.9	%	0-10
BASO %	.5	%	0-3

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LYMPH # 2.1 k/cmm 1.2-3.4
 MONO # .8 H k/cmm .1-.6
 GRAN # 7.7 H k/cmm 1.4-6.5
 EOS # .4 k/cmm 0-.7
 BASO # .1 k/cmm 0-.2

---- CHEMISTRY SERUM PROFILE ----

SERUM	10/26 2001 07:00	10/24 2001 10:08	10/24 2001 10:08	Units	Reference Ranges
NA	139.	141.		mmol/L	135-145
K	4.0	3.8		mmol/L	3.5-5
CL	113. H	111.		mmol/L	95-111
CO2	20. L	18. L		mmol/L	22-31
GLUC	84.	110.		mg/dl	65-110
BUN	17.	50. H		mg/dL	7-21
CREAT	1.1	1.7 H		mg/dL	.5-1.5
ANI GAP	6.0	12.0			2.99-19.1
AST	18.		25.	IU/L	5-42
ALT	20.		22.	IU/L	7-60
ALK P	78.		88.	IU/L	38-126
GGT	31.		39.	IU/L	15-73
T PROT	5.8 L		7.1	gm/dl	6-8.3
ALB	3.0 L		3.9	g/dl	3.1-5.5
T BILI	0.2		0.1	mg/dL	0-1.5
BIL,DIR				mg/dl	0-.4
BIL,UNC				mg/dl	.1-1.1
CA				mg/dL	9-10.6
PHOS				mg/dL	2.4-4.4
MG	2.1			mg/dL	1.7-2.2
ALC				mg/dl	
AMY			60.	U/L	30-110
LIP			254.	U/L	23-300
URIC				mg/dL	3.5-8.5
PREALBU				mg/dl	19-37
KETONES					
OSMOL				mOsm/kg	280-300
IRON				ug/dl	49-181
TIBC				ug/dl	250-450
%FE SAT				%	12-57
FERRITI				ng/mL	18-464
B12				pg/ml	157-1059
FOLATE				ng/ml	5.3-14.2
B12-RIA				pg/mL	211-911
FOL-RIA				ng/mL	2.6->20

Comments: a

a. Evaluation for GGT:

Effective 1/14/99 GGT reference range change to 15-73 IU/L.
 Patient GGT values may be up to 20% lower than previous methodology.

---- MICROBIOLOGY ----

Accession: MICRO 01 6267

Received: Oct 26, 2001 12:49

Collection sample: GASTRIC MUCOSAL BIOPSY Collection date: Oct 26, 2001 12:49
 Site/Specimen: GASTROINTESTINAL MUCOUS MEMBRANE

Test(s) ordered: H PYLORI SCREEN (UREASE TEST) completed: Oct 27, 2001

* BACTERIOLOGY FINAL REPORT => Oct 27, 2001 TECH CODE: 1922

Bacteriology Remark(s):
 UREASE NEGATIVE 10-27

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CONFIDENTIAL NON-ENDOSCOPIC REPORT
PROCEDURE DATE/TIME: 10/26/01 09:14

PRE-EVALUATION: AVAILABLE MEDICAL RECORDS AND HEALTH SUMMARY WERE REVIEWED. A BRIEF HISTORY (INDICATION) AND REVIEW OF SYSTEMS OF MAJOR AREAS WERE OBTAINED, INCLUDING DRUG/LATEX ALLERGIES, SUBSTANCE ABUSE, ANALGESIA/SEDATION/ANESTHESIA DRUG REACTION, FOOD/SUBSTANCE/MEDICATIONS TAKEN TODAY, RESPIRATORY, CARDIOVASCULAR, NEUROLOGIC, AND OTHER DISORDERS. FINDINGS WERE DOCUMENTED IN ANALGESIA/SEDATION RECORD. A DIRECTED PHYSICAL EXAM INCLUDING AIRWAY, RESPIRATORY AND CARDIOVASCULAR AREAS WAS DONE. FINDINGS WERE DOCUMENTED IN THE SEDATION/ANALGESIA RECORD. THE PATIENT WAS FOUND TO BE FIT FOR ENDOSCOPY AND SEDATION/ANALGESIA, WITH POTENTIAL BENEFITS EXCEEDING RISKS. SEE IV CONSCIOUS SEDATION RECORD FOR FOCUSED HISTORY/INDICATION, INDICATION FOR PROCEDURE AND SEDATION/ANALGESIA, REVIEW OF SYSTEMS, PREVIOUS SEDATION/ANALGESIA OR ANESTHESIA COMPLICATIONS, ALLERGIES, CURRENT AND TODAY'S MEDICATIONS, PHYSICIAN EXAM OF LUNGS, AIRWAY, HEART, RISK (A.S.A.) AND RISK/BENEFIT ASSESSMENT.

CONSENT: AFTER EXPLANATION OF THE INDICATIONS, POTENTIAL COMPLICATIONS, AND AVAILABLE ALTERNATIVES FOR THE PROCEDURE AND SEDATION/ANALGESIA, AND AFTER GIVING OPPORTUNITY FOR QUESTIONS, INFORMED CONSENT WAS OBTAINED FROM THE PATIENT.

PREPARATION: PULSE, RESPIRATORY RATE, BLOOD PRESSURE, OXYGEN SATURATION, RESPONSE TO VERBAL COMMANDS, AND VASO-MOTOR SKIN RESPONSE WERE MONITORED.

MEDICATIONS: BEFORE AND DURING THE PROCEDURE, MEDICATIONS WERE CAREFULLY TITRATED TO A TOTAL OF: - DROPERIDOL 10 MG IV BEFORE THE PROCEDURE - FENTANYL 100 MCG IV BEFORE THE PROCEDURE - VERSED 2 MG IV BEFORE THE PROCEDURE

PROCEDURE: THE ENDOSCOPE WAS PASSED WITH EASE UNDER DIRECT VISUALIZATION TO THE 2ND PORTION OF THE DUODENUM. RETROFLEXION WAS PERFORMED.

FINDINGS: HYPOPHARYNX: THE HYPOPHARYNX APPEARED NORMAL. ESOPHAGUS: THE ESOPHAGUS WAS NORMAL IN APPEARANCE AND THERE WAS NO EVIDENCE OF ESOPHAGITIS, INTRINSIC MASS, EXTRINSIC COMPRESSION, ESOPHAGEAL VARICES, RING, WEB, STRICTURE, MOTOR DISTURBANCE, BARRETT'S EPITHELIUM, DIVERTICULA, OR BLEEDING. GE-JUNCTION: STOMACH: THERE WAS A SINGLE NON-BLEEDING PALE CRATERED ULCER AT THE PYLORUS WHICH SHOWED NO STIGMATA OF RECENT HEMORRHAGE. A BIOPSY WAS OBTAINED AND PLACED IN CLO TEST AGAR. THERE WERE A FEW NON-BLEEDING SUPERFICIAL ULCERS IN THE ANTRUM WHICH SHOWED NO STIGMATA OF RECENT HEMORRHAGE. PYLORUS: THE PYLORUS APPEARED NORMAL. DUODENUM: THERE

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WAS A SINGLE NON-BLEEDING SUPERFICIAL ULCER IN THE 2ND PORTION OF THE DUODENUM.

IMPRESSION: 1. THE HYPOPHARYNX APPEARED NORMAL. 2. THE ESOPHAGUS APPEARED NORMAL. 3. SINGLE NON-BLEEDING PALE ULCER AT THE PYLORUS. 531.3. 4. A FEW NON-BLEEDING SUPERFICIAL ULCERS IN THE ANTRUM. 531.3. 5. THE PYLORUS APPEARED NORMAL. 6. SINGLE NON-BLEEDING SUPERFICIAL ULCER IN THE DUODENUM.

RECOMMENDATION: - FOLLOW-UP ON THE RESULTS OF THE CLO TEST. - BEGIN TAKING THE FOLLOWING MEDICATIONS: - PROTON PUMP INHIBITOR THERAPY - AVOID NSAIDS/ASA. - REPEAT EGD 8-10 WEEKS TO CHECK ULCER HEALING PERFORMED

Individual Safety Report



3824176-X-00-06

DSS

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

Approved 1 - FDA on 09/25/95

Mfr report #	001-0981-M0108799
UP/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient identifier [Redacted]	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight _____ lbs or Unk _____ 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 _____ (month/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 checked="" type="checkbox"/> other: <u>Impt. Med. Event</u>	
3. Date of event (month/day/yr) Unknown	4. Date of this report (month/day/yr) 11/12/01		
5. Describe event or problem			
<p>This male consumer with a history of taking Aspirin (acetylsalicylic acid) for an unknown reason, Prevacid (lansoprazole) for acid reflux disease, allergic rhinitis and chronic sinus problems, back surgery in 1978 with residual back pain and being celibate for many years was started on Lipitor (atorvastatin) 10mg daily in Mar97 after a heart scan showed an unspecified amount of blockage. On an unknown date, unclear if before or after starting on Lipitor he experienced emotional lability, urinary frequency and urgency, malaise, and dry skin. In Oct97 his low-density lipoprotein levels dropped. On an unknown date Ginkgo Biloba was started to treat his malaise described as low energy level which he suspects was due to caring for his chronically ill wife. In Mar99 he developed bleeding in his colon and was hospitalized for colon surgery. In Mar99 he had 2.5 feet of colon removed because of the bleed. He suspects Aspirin and Ginkgo Biloba use contributed to his bleed and the Ginkgo Biloba was discontinued and the Aspirin was stopped due to his bleed. In Mar99 after surgery for the bleed in his colon, he</p>			
6. Relevant tests/laboratory data, including dates			
Mar97: Heart scan showing unspecified amount of blockage			
Oct97: Low density lipoprotein levels dropping			
Mar00: Angiogram showed 40 percent blockage			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol) use, hepatic/renal dysfunction, etc.)			
Residual back pain (present): Back surgery in 1978			
Allergic rhinitis with chronic sinus problems (present): Has had for over 40 years			
Acid reflux disease (present): Has had for a number of years took Prevacid			
Celibacy (past): Previous 19 years due to wife's illness			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeled, if known)			
#1 ATORVASTATIN (ATORVASTATIN)			
#2 (NIACIN) (NICOTINIC ACID) <u>Cont</u>			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) (month/yr or best estimate)	
#1 10 mg (Daily), Per oral		#1 03/ /97 - / /01	
#2 Unknown (Unknown), Per		#2 03/ /00 - / /01	
4. Diagnosis for use (indication)			5. Event abated after use stopped or dose reduced
#1 CORONARY ARTERY BLOCKAGE			#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 CORONARY ARTERY BLOCKAGE			#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1) (LANSOPRAZOLE) <u>Unknown - Stopped</u>			

G. All manufacturers			
1. Contact office - name/address (& mfring site for devices)		2. Phone number	
WWS PFIZER PHARMACEUTICALS 235 EAST 42ND STREET NEW YORK NY 10017 USA (Initial Unit)		(212) 573-3129	
4. Date received by manufacturer (month/day/yr) 11/05/01		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	
9. Mfr. report number 001-0981-M0108799		<input type="checkbox"/> user facility	
		<input type="checkbox"/> company representative	
		<input type="checkbox"/> distributor	
		<input type="checkbox"/> other:	
		8. Adverse event term(s)	
		1) EMOTIONAL LABILITY	
		2) URINARY FREQUENCY	
		3) MALAISE	
		4) DRY SKIN	
		5) DECREASED LD	
		6) HEMORRHAGE COLON	
		7) ECZEMA	

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



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

Approved by FDA on 06/20/95

Mfr report # 001-0981-M(108799) LP/DAI report # FDA Use Only

A. Patient information

1. Patient identifier, 2. Age at time of event, 3. Sex, 4. Weight

B. Adverse event or product problem

1. Adverse event and/or Product problem, 2. Outcomes attributed to adverse event, 3. Date of event, 4. Date of this report

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions

C. Suspect medication(s)

1. Name, 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

G. All manufacturers

1. Contact office - name/address, 2. Phone number, 3. Report source, 4. Date received by manufacturer, 5. (A)NDA #, IND #, PLA #, 6. If IND, protocol #, 7. Type of report, 8. Adverse event term(s), 9. Mfr. report number

E. Initial reporter

1. Name, address & phone #, 2. Health professional?, 3. Occupation, 4. Initial reporter also sent report to FDA

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



3825163-8-00-04

B. Adverse event or product problem

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

developed a full body rash described as eczema. In Mar00 he switched cardiologists and the new cardiologist ran a routine angiogram which showed 40 percent blockage. It is unknown if this 40 percent blockage is more or less than the blockage shown on the Mar97 blockage. In Mar00 Niacin (nicotinic acid), Zestril (lisinopril), Aspirin and folic acid were started to more aggressively treat his blockage. On an unknown date Prevacid was switched to Prilosec (omeprazole) to treat his acid reflux. In 2000 he experienced headaches which he attributes to his worsening allergic rhinitis and chronic sinusitis. The worsening allergic rhinitis and chronic sinusitis caused him to wake up more during the night. In 2001 Niacin was stopped because he did not like the way it made him feel. In 2001 Lipitor was increased to 40mg daily and Niacin was restarted again in order to more aggressively treat his blockage. In 2001, after his wife died he developed a relationship and discovered he was impotent and had decreased libido. On 29Oct01 Zestril was stopped because of his impotence and decreased libido. On 30Oct01 Lipitor was decreased to 20mg daily because of his impotence and decreased libido. After discontinuation of Zestril and decreasing the Lipitor his impotence improved and his libido increased. On 04Nov01, Niacin and Prilosec were discontinued due to impotence and decreased libido. As of 05Nov01 the events he has been experiencing for years have improved described as lessening of his allergic rhinitis and chronic sinusitis, decreased frequency of headaches and awakenings at night, improved emotional lability, decreased urinary frequency and urgency, lessening malaise, improved moisture in his skin, his eczema resolved and his impotence and decreased libido continue to improve. The patient suspects since all these events improved when the Lipitor was decreased the Lipitor must have contributed to these events. The patient suspects Zestril contributed some to his impotence and decreased libido. He suspects Prilosec and Niacin was also contributing to his impotence and decreased libido.

C. Suspect medication (Cont...)

- Seq No. : 1
- C.1 Suspect medication : ATORVASTATIN (ATORVASTATIN)
- C.2 Dose, frequency & route used : 2) 40 mg (Daily), Per oral
3) 20 mg (Daily), Per oral
- C.3 Therapy Dates (or duration) : 2) / /01 - 10/30/01
3) 10/30/01 - Ongoing

- Seq No. : 2
- C.1 Suspect medication : (NIACIN) (NICOTINIC ACID)
- C.2 Dose, frequency & route used : 1) Unknown (Unknown), Per oral
2) Unknown (Unknown), Per oral
- C.3 Therapy Dates (or duration) : 2) / /01 - 11/04/01

- Seq No. : 5
- C.1 Suspect medication : (ASPIRIN) (ACETYLSALICYLIC ACID)
- C.2 Dose, frequency & route used : 1) Unknown (Unknown), Per oral
2) Unknown (Unknown), Per oral
- C.3 Therapy Dates (or duration) : 2) 03/ /00 - Unknown

C10. Concomitant medical products

- Seq No. : 1
- Concomitant Medical Product : (LANSOPRAZOLE)
- Dose, frequency & route used : 1) Unknown

G. All manufacturers

8. Adverse event term(s)

- 8) CORONARY ARTERY BLOCKAGE
- 9) HEADACHES
- 10) WORSENING RHINITIS
- 11) INCREASED WAKEFULNESS
- 12) UNSPECIFIED SIDE EFFECTS
- 13) IMPOTENCE
- 14) DECREASED LIBIDO
- 15) URINARY URGENCY
- 16) WORSENING CHRONIC SINUSITIS



Merck Human Health Division

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

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

NO ASSIGNMENT

Mfr report #	WAES 01114006
UF/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient identifier 	2. Age at time of event: or <u>56 years</u> Date of Birth:	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight Unk
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or		<input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> life-threatening	<input checked="" type="checkbox"/> hospitalization-initial or prolonged	<input checked="" type="checkbox"/> other: <u>important medical</u>	
3. Date of event (mo/day/yr)	<u>08/01/01</u>	4. Date of this report (mo/day/yr)	<u>11/15/01</u>
5. Describe event or problem			
A Multicenter, Randomized, Controlled, Double-Blind Trial to Investigate the Clinical Efficacy and Tolerability of Early Treatment with Simvastatin 40 mg daily for 30 days, Followed by Simvastatin 80 mg Daily Thereafter in Tirofiban-Treated Acute Coronary Syndrome Patients who have been Randomized to Receive Enoxaparin or Unfractionated Heparin in Conjunction with Aspirin, and in Optimally-Treated ST Elevation Acute Coronary Syndrome Patients			
Information has been received from an investigator concerning a 56 year old female with acute myocardial infarction who entered a study, title as stated above. On 31-JUL-2001 the patient entered the A-phase of the trial and was placed on therapy with injection (form) (start 31-JUL-2001 through 01-AUG-2001) for the treatment of acute myocardial infarction (dose not reported). Concomitant therapy included heparin (start 31-JUL-2001 through 02-AUG-2001) and aspirin. On 01-AUG-2001 the patient experienced chest pain, absence of pulse lower extremity, cath site bleed and hematuria.			
(Continued on Additional Page)			
6. Relevant tests/laboratory data, including dates			
Refer to Additional Page			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)			
CONCURRENT CONDITIONS: acute myocardial infarction			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeier, if known)			
# 1 INJ AGGRASTAT Unk			
# 2 infusion (form) heparin Unk			
(Continued on Additional Page)			
2. Dose, frequency & route used		3. Therapy dates (from/to, if unknown, give duration)	
# 1 Unk/Unk/IV		# 1 07/31/01 - 08/01/01	
# 2 Unk/Unk/IV		# 2 07/31/01 - 08/02/01	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
# 1 acute myocardial infarction		yes no N/A unk	
# 2 acute myocardial infarction		# 1 <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
# 1		# 2 <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
# 2		# 1 <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
# 2		# 2 <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
6. Lot # (if known)		7. Exp date (if known)	
# 1		# 1	
# 2		# 2	
9. NDC # - for product problems only (if known)			
Unknown			
10. Concomitant medical products and therapy dates (exclude: treatment of event)			

G. All manufacturers	
1. Contact office - name/address	
Merck Human Health Division Merck & Co., Inc. P.O. Box 4 West Point, PA 19486-0004 ATTN: Worldwide Product Safety	
2. Phone Number (484)344-2416	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign <input checked="" type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other	
4. Date received by manufacturer (mo/day/yr)	5. (A)NDA # 20912
<u>11/08/01</u>	IND
6. If IND, protocol #	PLA #
<u>1800018</u>	pre-1938 <input type="checkbox"/> yes
7. Type of report	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> Follow-up#	9. Mfr. report number
	WAES 01114006
8. Adverse event term(s)	
PERIPHERAL PULSE ABSENT; ANEMIA; CATHETER SITE BLEEDING; CATHETER SITE BLEEDING; VENTRICULAR TACHYCARDIA; CHEST PAIN; UPPER GASTROINTESTINAL HEMORRHAGE; HEMATURIA	

E. Initial reporter			
1. Name, address & phone #			
NOV 21 2001			
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	

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



3829487-X-00-02

On 02-AUG-2001 the patient experienced hematemesis, anemia and (another) cath site bleed. The anemia and absence of peripheral pulses caused prolongation of hospitalization. On 02-AUG-2001, the patient underwent: 1. Aortogram, 2. Selective right iliac angiography, 3. Right iliac artery angioplasty, 4. Right iliac artery stenting, resulting in successful endovascular intervention to a right iliac artery dissection restoring normal flow with balloon angioplasty and stenting. On 06-AUG-2001 the patient experienced ventricular tachycardia and hospitalization was prolonged. Subsequently, the patient recovered from chest pain, absence of pulse lower extremity, cath site bleed, hematuria, hematemesis, anemia, the second episode of cath site bleed and ventricular tachycardia. This patient did not enter the 2-phase of the trial. The reporting investigator felt that anemia, cath site bleeds, hematuria and hematemesis were related to study therapy and that the chest pain, absence of pulse lower extremity, and ventricular tachycardia were not. Chest pain, cath site bleed, hematuria, hematemesis and cath site bleed were considered to be an other important medical event.

Relevant laboratory values included the following:

31-Jul-2001 blood hemoglobin test 12.8 gm/dl 12.0 to 16.0
 01-Aug-2001 blood hemoglobin test 11.5 gm/dl 12.0 to 16.0 Low
 01-Aug-2001 blood hemoglobin test 11.7 gm/dl 12.0 to 16.0 Low
 01-Aug-2001 blood platelet count 204
 01-Aug-2001 blood hemoglobin test 10.6 gm/dl 12.0 to 16.0 Low
 01-Aug-2001 blood platelet count 186
 01-Aug-2001 blood platelet count 198
 02-Aug-2001 blood hemoglobin test 10.4 gm/dl 12.0 to 16.0 Low
 02-Aug-2001 blood hemoglobin test 10.1 gm/dl 12.0 to 16.0 Low
 02-Aug-2001 blood hemoglobin test 8.8 gm/dl 12.0 to 16.0 Low
 02-Aug-2001 blood hemoglobin test 9.7 gm/dl 12.0 to 16.0 Low
 02-Aug-2001 blood platelet count 143
 02-Aug-2001 blood platelet count 187
 03-Aug-2001 blood hemoglobin test 9.0 gm/dl 12.0 to 16.0 Low
 03-Aug-2001 blood platelet count 141
 04-Aug-2001 blood hemoglobin test 8.3 gm/dl 12.0 to 16.0 Low
 04-Aug-2001 blood platelet count 139 Low
 04-Aug-2001 blood hemoglobin test 10.2 gm/dl 12.0 to 16.0 Low
 05-Aug-2001 blood hemoglobin test 10.5 gm/dl 12.0 to 16.0 Low
 05-Aug-2001 blood platelet count 185
 06-Aug-2001 blood hemoglobin test 10.8 gm/dl 12.0 to 16.0 Low
 06-Aug-2001 blood platelet count 212
 07-Aug-2001 blood hemoglobin test 10.9 gm/dl 12.0 to 16.0 Low
 07-Aug-2001 blood hemoglobin test 11.4 gm/dl 12.0 to 16.0 Low
 07-Aug-2001 blood platelet count 210
 07-Aug-2001 blood platelet count 224
 08-Aug-2001 blood hemoglobin test 11.1 gm/dl 12.0 to 16.0 Low
 08-Aug-2001 blood platelet count 235

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value Unit	Normal Range
angiography Comment: right iliac artery normal flow restored with balloon angioplasty and stenting	08/02/01		
peripheral arterial angioplasty Comment: right iliac artery normal flow restored with balloon angioplasty and stenting	08/02/01		
vascular stent placement Comment: right iliac artery normal flow restored with balloon angioplasty and stenting	08/02/01		
transfemoral aortography Comment: right iliac artery normal flow restored with balloon angioplasty and stenting	08/02/01		

LABORATORY RESULTS

Tests	Date	Value Unit	Normal Range
hemoglobin	07/31/01	12.8 gm/dl	12.0 - 16.0
hemoglobin Comment: Low	08/01/01	11.5 gm/dl	12.0 - 16.0
hemoglobin Comment: Low	08/01/01	11.7 gm/dl	12.0 - 16.0
hemoglobin Comment: Low	08/01/01	10.6 gm/dl	12.0 - 16.0
platelet count	08/01/01	198	
platelet count	08/01/01	198	

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platelet count	08/01/01	186	
hemoglobin	08/02/01	10.4 gm/dl	12.0 - 16.0
Comment: Low			
hemoglobin	08/02/01	10.1 gm/dl	12.0 - 16.0
Comment: Low			
hemoglobin	08/02/01	8.3 gm/dl	12.0 - 16.0
Comment: Low			
hemoglobin	08/02/01	9.7 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/02/01	187	
platelet count	08/02/01	143	
hemoglobin	08/03/01	9.0 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/03/01	141	
hemoglobin	08/04/01	8.3 gm/dl	12.0 - 16.0
Comment: Low			
hemoglobin	08/04/01	10.2 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/04/01	139	
Comment: Low			
hemoglobin	08/05/01	10.5 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/05/01	185	
hemoglobin	08/06/01	10.8 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/06/01	212	
hemoglobin	08/07/01	10.9 gm/dl	12.0 - 16.0
Comment: Low			
hemoglobin	08/07/01	11.4 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/07/01	224	
platelet count	08/07/01	210	
hemoglobin	08/08/01	11.1 gm/dl	12.0 - 16.0
Comment: Low			
platelet count	08/08/01	235	

C. Suspect medication(s)

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

#3 aspirin Unk

2. Dose, frequency & route used

#3 Unk/Unk/Unk

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

#3 Unk

4. Diagnosis for use (indication)

#3 Unknown

5. Event abated after use stopped or dose reduced

YES NO N/A UNK

#3 X

6. Lot # (if known)

#3

7. Exp date (if known)

#3



NOV 26 2001

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8. Event reappeared after reintroduction

	YES	NO	N/A	UNK
#3				X



NOV 26 2001

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WAES Number: 01114006

PAGE 1

Suspect Drug: L-644,128

Evaluation: anemia

Date:

Previous Submissions

<u>WAES Number</u>	<u>Date(s) Sent To FDA</u>
89100368	04/09/90
90011160	02/05/90
	03/20/90
	03/30/90
90030010	03/08/90
	03/23/90
90040665	04/25/90
90100137	10/11/90
	07/17/91
91060610	06/13/91
	07/24/91



DOB
NOV 26 2001

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WAES Number: 01114006

PAGE 2

Suspect Drug: L-644,128

Evaluation: catheter site bleeding

Date:

Previous Submissions

WAES Number

Date(s) Sent To FDA

01094001

09/21/01



DSS
NOV 21 2001

NOV 21 2001

WAES Number: 01114006
Suspect Drug: L-644,128
Evaluation: chest pain
Date:

Previous Submissions

<u>WAES Number</u>	<u>Date(s) Sent To FDA</u>
86040721	05/06/86
	06/27/86
86090182	09/19/86
	10/16/86
	11/04/86
86100659	11/04/86
	12/17/87
87020021	02/09/87
87040178	04/15/87
87040594	05/01/87
87050143	05/26/87
89090121	09/12/89
	12/12/90
	01/04/91
89120465	12/18/89
89120742	12/29/89
	02/26/90
	06/13/90
	03/14/91
	01/08/92
	09/28/93
90090194	09/13/90
	09/17/91
91030561	07/31/91
	09/04/91
	09/11/91
91080457	01/28/92



035
NOV 26 2001

NOV 21 2001

WAES Number: 01114006

PAGE 4

Suspect Drug: L-644,128

Evaluation: hematuria

Date:

Previous Submissions

<u>WAES Number</u>	<u>Date(s) Sent To FDA</u>
87060162	06/19/87
89010151	01/10/89
	01/24/89
	02/08/89
	04/14/89
89100778	10/31/89
	12/06/89
90010902	01/30/90
	09/27/90
91030561	07/31/91
	09/04/91
	09/11/91
91031131	03/26/91
	05/02/91
91070840	07/19/91



NOV 26 2001

NOV 21 2001

WAES Number: 01114006

PAGE 5

Suspect Drug: L-644,128

Evaluation: peripheral pulse absent

Date:

Previous Submissions

WAES Number

Date(s) Sent To FDA

None

Individual Safety Report



3829487-X-00-09

NOV 26 2001

NOV 21 2001

WAES Number: 01114006

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Suspect Drug: L-644,128

Evaluation: upper gastrointestinal hemorrhage

Date:

Previous Submissions

WAES Number

Date(s) Sent To FDA

00074039

08/08/00



3829487-X-00-10

NOV 21 2001

NOV 21 2001

WAES Number: 01114006

PAGE 7

Suspect Drug: L-644,128

Evaluation: ventricular tachycardia

Date:

Previous Submissions

WAES Number

89020246

Date(s) Sent To FDA

02/13/89

04/24/89



NOV 21 2001

NOV 21 2001



Voluntary reporting of events and product problems

FDA Use Only
 Triage unit sequence # **156253**

et Submission - Page 1 of 2

A. Patient information

1. Patient Identifier: [redacted] 2. Age at time of event: **61 Years** 3. Sex: female male 4. Weight: _____ lbs or _____ kgs

In confidence

B. Adverse event or product problem

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

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

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

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

3. Date of event (mo/day/yr) **08/14/2001** 4. Date of this report (mo/day/yr) **11/27/2001**

5. Describe event or problem

This patient had initially been admitted to r/o bacteremia. His hospital stay was complicated due to an episode of hemoptysis vs. hematemesis. Underwent work up and ASA discontinued.

6. Relevant tests/laboratory data, including dates

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 MEDWATCH CTU**

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

endstage renal disease; DM

**MEDWATCH
 NOV 27 2001**

C. Suspect medication(s)

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

#1 **Aspirin 325 mg**

#2 _____

2. Dose, frequency & route used

#1 **325 daily Oral**

#2 _____

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

#1 _____

#2 _____

4. Diagnosis for use (indication)

#1 _____

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____

#2 _____

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

bisacodyl, CaCO3, clotrimazole cream, insulin, lactulose, lisinopril, metoprolol, minoxidil, Nephrocaps, NTG patch, sevelamer

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)

NOV 27

E. Reporter (see confidentiality section on back)

1. Name & address phone # _____

PharmD
 VA Pittsburgh Healthcare System - 132M-H-, 7183 Highland Drive
 Pittsburgh Pennsylvania 15206
 United States _____ med.va.gov

2. Health professional? yes no

3. Occupation **Pharmacist**

4. Also reported to

manufacturer user facility distributor

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



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

CTU 156253

Individual Safety Report



3830911-7-00-02

156253

WATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5 of 2 of 2

C10. Concomitant medical products and therapy dates continued

, simvastatin

D10. Concomitant medical products and therapy dates continued

DSS

NOV 28 2001

Mail to: MEDWATCH or FAX 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.

156253



3830912-9-00-01

**Voluntary reporting of
adverse events and product problems**

Submission - Page 1

FDA Use Only	
Triage unit sequence #	156254

A. Patient information

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

In confidence

B. Adverse event or product problem

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

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

<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) 08/28/2001	4. Date of this report (mo/day/yr) 11/27/2001
--	--

5. Describe event or problem

This patient presented with c/o lightheadedness and was determined to be orthostatic, anemic, and had heme + stools. Gastric lavage was also heme +. He was admitted to ICU for transfusions and work up. He was determined to have antral and duodenal ulcers.

6. Relevant tests/laboratory data, including dates

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MEDWATCH CTU

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

chronic renal insufficiency; BPH; hypercholesterolemia; EtOH abuse

MEDWATCH
NOV 27 2001

C. Suspect medication(s)

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

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
6. model #	5. Expiration date (mo/day/yr)
catalog #	7. If implanted, give date (mo/day/yr)
serial #	8. If explanted, give date (mo/day/yr)
lot #	
other #	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
DSS	
NOV 28 2001	

E. Reporter (see confidentiality section on back)

1. Name & address	phone #	
[redacted] PharmD	[redacted]	
VA Pittsburgh Healthcare System - 102M-H- 7180 Highland Drive Pittsburgh Pennsylvania 15206 United States [redacted] ed.va.gov		
2. Health professional?	3. Occupation	4. Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacist	<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 20854
or FAX to: 1-800-FDA-0178

CTU 156254

Individual Safety Report



3831039-2-00-01

VOLUNTARY reporting
 of adverse
 events and product problems

FDA Use only

156299

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event: 69	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 200 lbs kgs
In confidence	Date of birth		

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: 6/21/01

life threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other: _____

3. Date of event: 6/21/01

4. Date of this report: 11/19/01

114/4 GI Bleed (aspirin) 69 year old male presented to outside hospital with chest pain, mild hypotension, episode of coffee ground emesis, some confusion, weakness, hematocrit of 45. Troponin was slightly elevated at 1.1, elevated PT and PPT. EKG showed acute ST-T wave changes and he was transferred to this hospital 6/21. He has history of gout and hypertension. Scr 1.5, platelets 122. He had subsequent chest pain and was found to have myocardial infarction. EKG showed significant ischemia. After admission, he had at least 250cc bright red blood per rectum. INR 1.79, myoglobin 510, troponin 1.01, hematocrit 41. He has no history of taking Coumadin. He was emergently intubated. He was unresponsive, pulseless, hypoxic with acidosis, likely secondary to massive gastrointestinal bleed complicated by a massive myocardial infarction. He had no history of gastrointestinal bleed in the past. Treatment of the MI was to require anticoagulants and so was not done. Family requested no further heroic measures. He expired same day after the massive MI. Home meds included allopurinol, aspirin, Ziac, Zestril. (possible 2)

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MEDWATCH CTU

CTU 156299

C. Suspect medication(s)

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

2. Dose, frequency & route used

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

4. Diagnosis for use (indication)

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
 #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)

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)

NOV 28 2001

E. Initial reporter

1. Name, address & phone #
 [Redacted]
 Dept. Pharmacy
 Road

2. Health professional?
 pharmacist:

3. Occupation

4. Also reported to
 manufacturer
 user facility
 distributor



ie by user-facilities, s and manufacturers for MANDATORY reporting

Mfr report # US-01-107-00
UP/Dist report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information
1. Patient identifier
2. Age at time of event: 70
3. Sex: male
4. Weight: lbs or 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: 11/uk/01
4. Date of this report: 11/19/01

5. Describe event or problem: perforated peptic ulcer
Reported Term: perforated peptic ulcer
Coded Term: ulcer peptic per

6. Relevant tests/laboratory data, including dates: June 2001 platelet count 684,000 cell/mm3; 3 October 2001 platelet count 251,000 cell/mm3; 11 October 2001 platelet count 568,000 cells/mm3

7. Other relevant history, including preexisting medical conditions: coronary artery bypass due to ischemic heart disease; hypertension; lower GI hemorrhage in April 2001

C. Suspect medication(s)
1. Name (give labeled strength & mfr/labeler, if known): #1 AGRYLIN, #2 PREDNISONE
2. Dose, frequency & route used: #1 0.5 mg twice a day, #2 20 mg daily
3. Therapy dates: #1 08 June 20 - unknown, #2 unknown - unknown
4. Diagnosis for use: #1 Essential Thrombocy, #2 hemolytic anemia
5. Event abated after use: #1 doesn't apply, #2 doesn't apply
6. Lot #: #1 unknown, #2 unknown
7. Exp. date: #1 unknown, #2 unknown
8. Event reappeared after reintroduction: #1 doesn't apply, #2 doesn't apply
9. NDC #: -
10. Concomitant medical products: albuterol inhaler 2 puffs as needed; Lotensin (benazepril) dose & therapy dates unavailable; Lipitor (atorvastatin) dose & therapy dates unavailable; Norvasc (amlodipine) dose and therapy dates unava lable

D. Suspect medical device
1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device: health professional, lay user/patient, other
5. Expiration date
6. model #, catalog #, serial #, lot #, other #
7. If implanted, give date
8. If explanted, give date
9. Device available for evaluation?
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter
1. Name, address & phone #: Dr. [redacted] St [redacted] [redacted]
2. Health professional? yes
3. Occupation: hematologist
4. Initial reporter also sent report to FDA: 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.

DEC 05 2001



by user-facilities, and manufacturers for MANDATORY reporting page 2 of 5

Mfr report # US-01-107-00 UF/Clst report # FDA Use Only

MILL THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 70 or Date of birth: [redacted]

3. Sex: female male

4. Weight: [redacted] lbs or [redacted] kgs

B. Adverse event or product problem

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

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

3. Date of event (m/day/yr): 11/uk/01

4. Date of this report (m/day/yr): 11/19/01

5. Describe event or problem: Sec Attached

Reported Term	Coded Term
perforated peptic ulcer	ulcer peptic per

6. Relevant tests/laboratory data, including dates: June 2001 platelet count 684,000 cell/mm3; 3 October 2001 platelet count 251,000 cell/mm3; 11 October 2001 platelet count 568,000 cells/mm3

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.): coronary artery bypass due to ischemic heart disease; hypertension; lower GI hemorrhage in April 2001

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known): #1 ASPIRIN #2 [redacted]

2. Dose, frequency & route used: #1 325 mg daily #2 [redacted]

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

4. Diagnosis for use (indication): #1 unknown #2 [redacted]

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 [redacted]

7. Exp. date (if known): #1 unknown #2 [redacted]

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

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

10. Concomitant medical products and therapy dates (exclude treatment of event): albuterol inhaler 2 puffs as needed; Lotensin (benazepril) dose & therapy dates unavailable; Lipitor (atorvastatin) dose & therapy dates unavailable; Norvasc (amlodipine) dose and therapy dates available

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: [redacted]

5. Expiration date (m/day/yr): [redacted]

6. model #: [redacted] catalog #: [redacted] serial #: [redacted] lot #: [redacted] other #: [redacted]

7. If implanted, give date (m/day/yr): [redacted]

8. If explanted, give date (m/day/yr): [redacted]

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

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

E. Initial reporter

1. Name, address & phone #: Dr. [redacted] St [redacted] [redacted]

2. Health professional? yes no

3. Occupation: hematologist

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.

DEC 05 2001



Report does not constitute medical personnel, user, manufacturer or product attributed to the event.

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

Refer to guidelines for specific instructions

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FDA Use Only

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

1. Check one user facility distributor

2. UF/Dist report number

3. User facility or distributor name/address

4. Contact person

5. Phone Number

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

7. Type of report initial follow-up # _____

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

9. Approximate age of device

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

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

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

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

14. Manufacturer name/address

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)
 Tami Martin, RN Esq.
 Regulatory Affairs
 Shire Pharmaceutical Development Inc.
 1901 Research Blvd., Suite 500
 Rockville, MD 20850

2. Phone number
 240-453-6400

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

4. Date received by manufacturer (mo/day/yr)
 11/19/01

5. (A)NDA # 20333
 IND # _____
 PLA # _____
 pre-1938 yes
 OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)
 5-day 15-day
 10-day periodic
 Initial follow-up # 0

8. Adverse event term(s)
 Term/Reported Term/Coded
 perforated peptic ulcer ulcer peptic per

9. Mfr. report number
 US0110700

H. Device manufacturers only

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

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

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

4. Device manufacture date (mo/yr)

5. Labeled for single use?
 yes no

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

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

8. Usage of device
 initial use of device
 reuse
 unknown

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

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

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

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

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

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



Form 3500A Attachment

Case No.: US-01-107-00
Follow-Up: Initial
Patient: [REDACTED]
Event Date: 11/uk/01
Report Date: 11/19/01
Other Party TRK #: 27883MI
Suspect Medications 1 aspirin
 2

B-5

Adverse experience: perforated peptic ulcer (ulcer peptic per)

A hematologist provided the following information on 19 November 2001.

[REDACTED] a 70-year-old male, developed hemolytic anemia and was started (date unavailable) on prednisone 20 mg daily. On 8 June 2001 with a platelet count of 684,000 cell/mm³. The gentleman started treatment for Essential Thrombocythemia (ET) with Agrylin (anagrelide hydrochloride) 0.5 mg twice a day. His platelet count was 684,000 cell/mm³. On 3 October 2001 his platelet count was 251,000 cell/mm³ resulting in interruption of Agrylin therapy. Agrylin was restarted on 11 October 2001 when his platelet count was 568,000 cells/mm³. In November while in Greece, he was admitted to the hospital with a perforated peptic ulcer.

[REDACTED] medical history included coronary artery bypass due to ischemic heart disease, hypertension, lower gastrointestinal hemorrhage in April 2001 (INR 3.5 while on warfarin therapy). Concomitant medications included albuterol inhaler 2 puffs as needed; Lotensin (benazepril) dose unavailable; Lipitor (atorvastatin) dose unavailable; Norvasc (amlodipine) dose unavailable; aspirin 325 mg daily.

The reporting physician considered aspirin, prednisone and Agrylin as suspect medications.
Outcome: unknown
Expectedness: unlabeled

01/19/01



Form 3500A Attachment

Case No.: US-01-107-00
 Follow-Up: Initial
 Patient: [REDACTED]
 Event Date: 11/uk/01
 Report Date: 11/19/01
 Other Party TRK #: 27883MI
 Suspect Medications: 1 AGRYLIN
 2 PREDNISONE

B-5

Adverse experience: perforated peptic ulcer (ulcer peptic per)

A hematologist provided the following information on 19 November 2001.

[REDACTED], a 70-year-old male, developed hemolytic anemia and was started (date unavailable) on prednisone 20 mg daily. On 8 June 2001 with a platelet count of 684,000 cell/mm³. The gentleman started treatment for Essential Thrombocythemia (ET) with Agrylin (anagrelide hydrochloride) 0.5 mg twice a day. His platelet count was 684,000 cell/mm³. On 3 October 2001 his platelet count was 251,000 cell/mm³ resulting in interruption of Agrylin therapy. Agrylin was restarted on 11 October 2001 when his platelet count was 568,000 cells/mm³. In November while in Greece, he was admitted to the hospital with a perforated peptic ulcer.

[REDACTED] medical history included coronary artery bypass due to ischemic heart disease, hypertension, lower gastrointestinal hemorrhage in April 2001 (INR 3.5 while on warfarin therapy). Concomitant medications included albuterol inhaler 2 puffs as needed; Lotensin (benazepril) dose unavailable; Lipitor (atorvastatin) dose unavailable; Norvasc (amlodipine) dose unavailable; aspirin 325 mg daily.

The reporting physician considered aspirin, prednisone and Agrylin as suspect medications.
 Outcome: unknown
 Expectedness: unlabeled

1735

11/19/01



3835436-0-00-01

Trace unit
sequence: 156627

A. Patient information

1. Patient identifier 9787	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight — lbs or — kgs
-------------------------------	--	---	-----------------------------------

B. Adverse event or product problem

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

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

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

3. Date of event: 10-3-01 4. Date of this report: 10-

5. Describe event or problem

GI Bleed

states no ibuprofen
~2 weeks PTA

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 EC ASA ASPIRIN ENTERIC COATED
	#2 IBuprofen
2. Dose, frequency & route used	#1 90 dose unknown
	#2 PRN 800mg
3. Therapy dates (if unknown give duration)	#1 ?
	#2 chronic pain
4. Diagnosis for use (indication)	#1 ?
	#2 chronic pain
5. Event abated after use stopped or dose reduced	#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
6. Lot # (if known)	#1
	#2
7. Exp. date (if known)	#1
	#2
8. Event reappeared after reintroduction	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # (for product problems only)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. Suspect medical device

1. Brand name	DSS
2. Type of device	DEC 05 2001
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/d/yyyy)	
6. Model #	
7. If implanted, give date (m/d/yyyy)	
8. If explanted, give date (m/d/yyyy)	
9. Device available for evaluation? (Do not send to FDA)	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)

1. Name, address & phone #	V A MED CENTER PHARMACY (119) 1601 S. ... RD GAINESVILLE, FL 32609-119
2. Health professional?	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
3. Occupation	MD
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"/>

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CTU 156627

MEDWATCH CTU



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

FAX to: 1-800-FDA-0178

ODER



3836415-X-00-01

Initial Submission - Page 1

FDA Use Only
Triage unit sequence # <u>156741</u>

A. Patient information			
1. Patient identifier [redacted]	2. Age at time of event: 83 Years or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 125 lbs or kgs
In confidence			
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 (m/d/y) <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 09/26/2001 (m/d/y)	4. Date of this report 12/04/2001 (m/d/y)		
5. Describe event or problem gi bleed			
6. Relevant tests/laboratory data, including dates			
<p>RECEIVED DEC 05 2001 MEDWATCH CTU</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic or renal dysfunction, etc.)			
<p>MEDWATCH DEC 05 2001</p>			
CTU 156741			
<p>RECEIVED</p>			

C. Suspect medication(s)			
1. Name (give labeled strength & manufacturer, if known)			
#1 aspirin			
#2			
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)		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. 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			
9. NDC # (for product problems only)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
D. Suspect medical device			
1. Brand name			
2. Type of device			
3. Manufacturer name & address			4. Operator of device
			<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
6. model #			5. Expiration date (m/d/y)
catalog #			7. If implanted, give date (m/d/y)
serial #			8. If explanted, give date (m/d/y)
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (m/d/y)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

DSS

DEC 05 2001

E. Reporter (see confidentiality section on back)			
1. Name & address			phone #
[redacted]			[redacted]
United States			
2. Health professional?	3. Occupation		4. Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacist		<input type="checkbox"/> manufacturer <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



3839919-9-00-01

VOLUNTARY reporting of events and product problems

Page 1 of 1

FDAs Use Only

FDAs Use Only
FDAs Use Only
157327

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 80 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight or 49.8 kgs
-------------------------------------	--	---	-----------------------------

B. Adverse event or product problem

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

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

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

3. Date of event (month/y): 12/8/01

4. Date of this report (month/y): 12/15/01

5. Describe event or problem

Pt. experienced nausea & GI upset starting on 12/6/01 in nursing home - was admitted - endoscopy revealed a duodenal ulcer & active arterial bleed. Vioxx & ASA were DC'd; Pepcid & Prevacid started. Pt. Required a total of 12 units of packed RBC's and surgical intervention. She coded x2 in the ICU on 12/10/01 and was brought back. She remains in the ICU.

6. Relevant test/laboratory data, including dates

H. pylori ⊖

12/8/01 Hgb/HCT 7.0/21.9

12/9 Hgb/HCT 8.0/24.2

12/12/01 7.6/21.1

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

CFD

Severe disorder

MEDWATCH

CTV 157327 DEC 17 2001

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

#1 Vioxx 25mg QD - Merck

#2 ASA 325mg QD - Unknown

2. Dose, frequency & route used

#1 25mg QD PO

#2 325mg QD PO

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

#1 08/31/01 - 12/8/01

#2 ? - 12/8/01

4. Diagnosis for use (indicator)

#1 Arthritis

#2 CAD

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)

KCl 20mEq

~~Selegiline 200mg TID~~

Nortriptyline 10mg TID

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/y)

6. model # DEC 17 2001

7. If implicated, give date (month/y)

8. If explained, give date (month/y)

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

yes no returned to manufacturer on (month/y)

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

E. Reporter (see confidentiality section on back)

1. Name & address [redacted] phone # [redacted]

[redacted] Hospital

2. Health professional? yes no

3. Occupation
Pharmacy Resident

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.

DSS

DEC 17 2001

PLEASE TYPE OR USE BLACK INK

Individual Safety Report



3841653-6-00-01

VOLUNTARY reporting of adverse events and product problems

FDA Use Only

Triage unit sequence # 157500

Internet Submission - Page 1 of 2

A. Patient information

1. Patient Identifier: 8825
 2. Age at time of event: 73 Years
 3. Sex: female male
 4. Weight: 91 kgs

B. Adverse event or product problem

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

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

3. Date of event (m/day/yr): 05/09/2001
 4. Date of this report (m/day/yr): 12/17/2001

5. Describe event or problem:
 Significant epistaxis and GI bleed in patient taking low dose aspirin and warfarin with INR 2.9. Patient with dieulafoy lesion. Admitted to hospital for management.

6. Relevant tests/laboratory data, including dates:
 INR 2.9, Hct 27.6, Plt. 217

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 1. CAD 2. CHF 3. Afib s/p CVA 2/01, on coumadin 3. HTN 4. DM, type II 5. Gout 6. CRI, baseline Cr 2.4 7. h/o diverticulitis, s/p resection > 20 yrs ago 8. BPH 9. Hyperlipidemia 10. h/o RLL pneumonia 6/99 11. h/o epistaxis 4/01

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known):
 #1 Aspirin 81mg
 #2 Warfarin 5mg Dupont

2. Dose, frequency & route used:
 #1 81mg QD Oral
 #2 5mg QD Oral

3. Therapy dates (if unknown, give duration from to (or best estimate)):
 #1 04/04/2001 05/09/2001
 #2 02/07/2001 05/09/2001

4. Diagnosis for use (indication):
 #1 CAD
 #2 A-fib

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

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

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

9. NDC # (for product problems only):

10. Concomitant medical products and therapy dates (exclude treatment of event):
 ASA 81mg qd Atenolol 12.5mg qd
 Quinine 325mg qd Digoxin 0.125mg qd
 Lisinopril 20mg bid ISDN 20mg tid
 Amiodarone 4

D. Suspect medical device

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

E. Reporter (see confidentiality section on back)

1. Name & address: [Redacted] Pharm D
 VA PSHCS 1660 South Columbian Way
 Seattle Washington 98108
 United States @med.va.gov

2. Health professional? yes no
 3. Occupation: Pharmacist
 4. Also reported to:
 manufacturer
 user facility
 doctor

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

CTU 157500

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3841653-6-00-02

157500

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 52 of 2

C10. Concomitant medical products and therapy dates continued

00mg qd Simvastatin 10mg qd Furosemide 80mg AM, 40mg pm Glyburide 10mg bid
Allopurinol 100mg qd

D10. Concomitant medical products and therapy dates continued

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DEC 20 2001
MEDWATCH CTU

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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.

CTU 157500



3843295-5-00-01

Approved by FDA on 10/23/93

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence #

157517

Page 1 of 1

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight
[REDACTED] | AGE: 40 yrs | MALE | 82.6 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; required intervention to
initial or prolonged prevent impairment/damage
 other

3. Date of event | 4. Date of this report
12/05/01 | 12/17/01

5. Describe event or problem
LOWER GI BLEED

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

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

C. Suspect Medication(s)

1. Name
#1 : LOVENOX
#2 : ASPIRIN 81MG TAB, CHEWABLE

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

#2: 162MG PO | #2: 12/04/01-12/05/01

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

#2: | #2: [YES]

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

#1: | #1: | #1: []

#2: | #2: | #2: []

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
ALGIN AC/ALOR 80/MG TRI 20/VA BICARE CHW
PROBENECID 500MG TAB
PROPRANOLOL HCL 20MG TAB
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] PharmD
VA MEDICAL CENTER RT. 9 PHARMACY SERVICE (119)
MARTINSBURG, WEST VIRGINIA 25401 [REDACTED]

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. []

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

MEDWATCH

DEC 19 2001

CTU 157517



3843295-5-00-02

12-13

157517

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: LOVENOX

DATE OF EVENT: 12/3/01009:56

Section B, Part 6, Relevant Test/Laboratory Data Continued;

TEST: NEUT # RESULTS: H 11.3 x1000/uL H:6.8/L:11.9 COLLECTION DATE: 12/5/01006:00

TEST: LYMPH # RESULTS: 1.6 x1000/uL H:3.3/L:1.5 COLLECTION DATE: 12/5/01006:00

TEST: MONO # RESULTS: 1.0 x1000/uL H:1.2/L:1.1 COLLECTION DATE: 12/5/01006:00

TEST: EO # RESULTS: 0.2 x1000/uL H:.5/L:1.1 COLLECTION DATE: 12/5/01006:00

TEST: BASO # RESULTS: 0.0 x1000/uL H:.2/L:0 COLLECTION DATE: 12/5/01006:00

TEST: WBC RESULTS: H 14.2 K/uL H:9.7/L:14.3 COLLECTION DATE: 12/5/01006:00

TEST: RBC RESULTS: 5.42 M/uL H:5.56/L:4.24 COLLECTION DATE: 12/5/01006:00

TEST: HGB RESULTS: 14.7 G/dL H:16.9/L:13.2 COLLECTION DATE: 12/5/01006:00

TEST: HCT RESULTS: 44.0 %VOLUME H:50.5/L:39.5 COLLECTION DATE: 12/5/01006:00

TEST: MCV RESULTS: L 81.2 fL H:100.5/L:83.5 COLLECTION DATE: 12/5/01006:00

TEST: MCH RESULTS: L 27.1 pg H:33.8/L:27.3 COLLECTION DATE: 12/5/01006:00

TEST: MCHC RESULTS: 33.4 g/dL H:36/L:32 COLLECTION DATE: 12/5/01006:00

TEST: PLT RESULTS: H 403 K/uL H:400/L:130 COLLECTION DATE: 12/5/01006:00

TEST: RDW RESULTS: 14.8 % H:15.5/L:11.6 COLLECTION DATE: 12/5/01006:00

TEST: MPV RESULTS: 8.1 fL H:10.9/L:5.7 COLLECTION DATE: 12/5/01006:00

TEST: NEUT % RESULTS: 79.9 % H:82.8/L:41.6 COLLECTION DATE: 12/5/01006:00

TEST: LYMPH % RESULTS: 11.4 % H:44.2/L:9.5 COLLECTION DATE: 12/5/01006:00

TEST: MONO % RESULTS: 7.1 % H:16.9/L:1 COLLECTION DATE: 12/5/01006:00

TEST: EO % RESULTS: 1.3 % H:5/L:0 COLLECTION DATE: 12/5/01006:00

TEST: BASO % RESULTS: 0.3 % H:2/L:0 COLLECTION DATE: 12/5/01006:00

TEST: CHOLESTEROL RESULTS: H 260. MG/DL H:200/L: COLLECTION DATE: 12/5/01006:00

TEST: TRIGLYCERIDE RESULTS: H 560 MG/DL H:250/L:0 COLLECTION DATE: 12/5/01006:00

TEST: HDL RESULTS: 57. MG/DL COLLECTION DATE: 12/5/01006:00

TEST: LDL CHOLESTEROL RESULTS: calc MG/DL H:130/L: COLLECTION DATE: 12/5/01006:00

TEST: TROPONIN I RESULTS: <0.3 ng/mL H:2/L:0 COLLECTION DATE: 12/4/01023:54

TEST: CPK RESULTS: 134. IU/L H:170/L:55 COLLECTION DATE: 12/4/01023:54

TEST: TROPONIN I RESULTS: <0.3 ng/mL H:2/L:0 COLLECTION DATE: 12/4/01017:56

TEST: CPK RESULTS: 133. IU/L H:170/L:55 COLLECTION DATE: 12/4/01017:56

TEST: TROPONIN I RESULTS: <0.3 ng/mL H:2/L:0 COLLECTION DATE: 12/4/01015:19

TEST: CPK RESULTS: 127 IU/L H:170/L:55 COLLECTION DATE: 12/4/01015:19

TEST: TROPONIN I RESULTS: <0.3 ng/mL H:2/L:0 COLLECTION DATE: 12/4/01009:53

TEST: NEUT # RESULTS: H 9.2 x1000/uL H:6.8/L:1.3 COLLECTION DATE: 12/4/01009:53

TEST: LYMPH # RESULTS: 1.3 x1000/uL H:3.3/L:1.5 COLLECTION DATE: 12/4/01009:53

TEST: MONO # RESULTS: 0.5 x1000/uL H:1.2/L:1.1 COLLECTION DATE: 12/4/01009:53

TEST: EO # RESULTS: 0.1 x1000/uL H:.5/L:1.1 COLLECTION DATE: 12/4/01009:53

TEST: BASO # RESULTS: 0.0 x1000/uL H:.2/L:0 COLLECTION DATE: 12/4/01009:53

TEST: WBC RESULTS: H 10.2 K/uL H:9.7/L:4.3 COLLECTION DATE: 12/4/01009:53

TEST: RBC RESULTS: H 5.68 M/uL H:5.56/L:4.24 COLLECTION DATE: 12/4/01009:53

TEST: HGB RESULTS: 15.4 G/dL H:16.9/L:13.2 COLLECTION DATE: 12/4/01009:53

TEST: HCT RESULTS: 46.6 %VOLUME H:50.5/L:39.5 COLLECTION DATE: 12/4/01009:53

TEST: MCV RESULTS: L 82.0 fL H:100.5/L:83.5 COLLECTION DATE: 12/4/01009:53

TEST: MCH RESULTS: L 27.0 pg H:33.8/L:27.3 COLLECTION DATE: 12/4/01009:53

TEST: MCHC RESULTS: 33.0 g/dL H:36/L:32 COLLECTION DATE: 12/4/01009:53

TEST: PLT RESULTS: 363 K/uL H:400/L:130 COLLECTION DATE: 12/4/01009:53

TEST: RDW RESULTS: 15.0 % H:15.5/L:11.6 COLLECTION DATE: 12/4/01009:53

TEST: MPV RESULTS: 8.2 fL H:10.9/L:5.7 COLLECTION DATE: 12/4/01009:53

TEST: NEUT % RESULTS: 80.5 % H:82.8/L:41.6 COLLECTION DATE: 12/4/01009:53

TEST: LYMPH % RESULTS: 12.6 % H:44.2/L:9.5 COLLECTION DATE: 12/4/01009:53

TEST: MONO % RESULTS: 6.1 % H:16.9/L:1 COLLECTION DATE: 12/4/01009:53

TEST: EO % RESULTS: 1.4 % H:5/L:0 COLLECTION DATE: 12/4/01009:53

TEST: BASO % RESULTS: 0.5 % H:2/L:0 COLLECTION DATE: 12/4/01009:53

TEST: PT RESULTS: 10.9 SEC H:13.1/L:10.2 COLLECTION DATE: 12/4/01009:53

TEST: APTT RESULTS: 32.3 SEC H:35.7/L:23.5 COLLECTION DATE: 12/4/01009:53

TEST: LDH RESULTS: 490. U/L H:618/L:1313 COLLECTION DATE: 12/4/01009:53

TEST: GLUCOSE RESULTS: 98. MG/DL H:110/L:75 COLLECTION DATE: 12/4/01009:53

TEST: UREA N RESULTS: 10. MG/DL H:20/L:9 COLLECTION DATE: 12/4/01009:53

TEST: CREATININE RESULTS: 1.0 MG/DL H:1.5/L:.8 COLLECTION DATE: 12/4/01009:53

TEST: URIC ACID RESULTS: H 9.6 MG/DL H:8.5/L:3.5 COLLECTION DATE: 12/4/01009:53

TEST: SODIUM RESULTS: 140. MMOL/L H:145/L:137 COLLECTION DATE: 12/4/01009:53

TEST: POTASSIUM RESULTS: H 5.1 MMOL/L H:5/L:3.6 COLLECTION DATE: 12/4/01009:53

157517

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TEST: CHLORIDE RESULTS: 99.5 MMOL/L H:107/L:98 COLLECTION DATE: 12/4/01009:53
 TEST: CO2 RESULTS: 29.0 MMOL/L H:30/L:22 COLLECTION DATE: 12/4/01009:53
 TEST: MAGNESIUM RESULTS: 1.7 MG/DL H:2.3/L:1.6 COLLECTION DATE: 12/4/01009:53
 TEST: CALCIUM RESULTS: 10.1 MG/DL H:10.2/L:8.4 COLLECTION DATE: 12/4/01009:53
 TEST: PHOSPHORUS RESULTS: 3.2 MG/DL H:4.5/L:2.5 COLLECTION DATE: 12/4/01009:53
 TEST: PROTEIN, TOTAL RESULTS: 7.2 GM/DL H:8.2/L:6.3 COLLECTION DATE: 12/4/01009:53
 TEST: ALBUMIN RESULTS: 4.2 GM/DL H:5/L:3.5 COLLECTION DATE: 12/4/01009:53
 TEST: TOT. BILIRUBIN RESULTS: .7 MG/DL H:1.3/L:.2 COLLECTION DATE: 12/4/01009:53
 TEST: AST (SGOT) RESULTS: 36. IU/L H:59/L:17 COLLECTION DATE: 12/4/01009:53
 TEST: CPK RESULTS: 170. IU/L H:170/L:55 COLLECTION DATE: 12/4/01009:53
 TEST: ALKPHOS RESULTS: 81. IU/L H:126/L:38 COLLECTION DATE: 12/4/01009:53

Section C. Part 10. Concomitant Drugs Continued

RANTIDINE HCL 150MG TAB	12/04/01-12/05/01
NITROGLYCERIN 0.4MG TAB, SUBLINGUAL	12/04/01-12/05/01
NITROGLYCERIN 2% OINT, TOP	12/04/01-12/05/01
ALGIN AC/ALOH 80/MG TAB 20/XA BICARB TAB, CHEWABLE	12/04/01-12/05/01
ENOXAPARIN 60MG/0.5ML/STR INJ	12/04/01-12/05/01
ASPIRIN 81MG TAB, CHEWABLE	12/04/01-12/05/01

Individual Safety Report



3843295-5-00-03

157517

Individual Safety Report



3843716-8-00-01

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

VOLUNTARY reporting of adverse events and product problems

Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

FDA Use Only

Triage unit sequence # **157613**

A. Patient information

1. Patient identifier: 9933
 2. Age at time of event: 72 Years
 3. Sex: female male
 4. Weight: 89 lbs or 89 kgs

B. Adverse event or product problem

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

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

3. Date of event (m/day/yr): 12/07/2001
 4. Date of this report (m/day/yr): 12/18/2001

5. Describe event or problem:
 Gastrointestinal bleed requiring hospital admission for management.

6. Relevant tests/laboratory data, including dates:
 12/6/01 HCT 41, Platelets 175
 12/7/01 HCT 24, Platelets 137

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 CAD, s/p CABGx3 1994 Afib refuses coumadin, now on aspirin and plavix STH CHF EF >50%, +MR, + TR 10/30/01 COPD FEV1 51% predicted, Hyperlipidemia Tob Abuse Anxiety Paranoid Schizophrenia -very high functioning- ETOH abuse in past Presumptive squamous cell CA nose H/O GI bleed on coumadin -colonoscopy 10/30/01 severe

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known):
 #1 Clopidogrel (75mg)
 #2 Aspirin (81mg)

2. Dose, frequency & route used:
 #1 75mg QD Oral
 #2 81mg QD Oral

3. Therapy dates (if unknown, give duration from/to (or best estimate)):
 #1 10/31/2001 12/07/2001
 #2 10/31/2001 12/07/2001

4. Diagnosis for use (indication):
 #1 A-fib -refuses warfarin-
 #2 A-fib -refuses warfarin-

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):
 Lasix 80 QD Carvedilol 6.5 BID Digoxin 0.125 QD Nitro PRN

D. Suspect medical device

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

E. Reporter (see confidentiality section on back)

1. Name & address: Pharm D, VA PSHCS, 1660 South Columbian Way, Seattle, Washington 98108, United States, va.med.gov
 phone #:
 2. Health professional? yes no
 3. Occupation: Pharmacist
 4. Also reported to:
 manufacturer
 user facility
 other:
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:



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

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 157613

DEC 21 2001

DSS

DEC 24 2001

Individual Safety Report



3843716-8-00-02

MEDWATCH

157613

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page # 2 of 2

B7. Other relevant history, including preexisting medical conditions continued

multiple diverticula throughout the entire colon and medium size internal hemorrhoids

DSS
DEC 24 2001

Mail to: MEDWATCH or FAX 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.

157613

Individual Safety Report



3844281-1-00-01

Voluntary reporting
 of adverse
 events and product problems

Form Approved: OMB No. 0910-0291 Expires: 11/30/99
 See OMB statement on reverse

FDA Use Only

Triage unit
 sequence # **157740**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient Identifier [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):
 death Feb 2001 (m/d/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (m/d/yyyy) 2-21-01

4. Date of this report (m/d/yyyy) 3/01

5. Describe event or problem:
 GI bleed
 2-21-01

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.):
 Vase & TOH - "vase shift & scotch"
 NO Hx GI, CHF, HTN or renal dysf

CTU 157740

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 <u>Urox 12.5 mg qd</u>	#2 <u>EC ASA 81 mg qd</u>
2. Dose, frequency & route used	
#1 <u>EC ASA 81 mg qd</u>	#2 <u>Urox 12.5 mg qd</u>
3. Therapy dates (if unknown, give duration) (month or best estimate)	
#1 <u>on admission 1-15-01</u>	#2 <u>1-23-01 started</u>
4. Diagnosis for use (indication)	
#1 _____	#2 _____
5. Event abated after use stopped or dose reduced	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	
#1 _____	#2 _____
7. Exp. date (if known)	
#1 _____	#2 _____
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input 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)	
#1 _____	#2 _____
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. Suspect medical device

1. Brand name _____

2. Type of device _____

3. Manufacturer name & address _____

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

5. Expiration date (m/d/yyyy) _____

6. model # _____

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

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

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

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

E. Reporter (see confidentiality section on back)

1. Name & address _____ 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.

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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.

DEC 27 2001

OK

Individual Safety Report



3844282-3-00-012

VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 11/2009 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

157741

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 0088

A. Patient information

1. Patient identifier [redacted] in confidence	2. Age at time of event: 44 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	--	---	---

B. Adverse event or product problem

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

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

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

3. Date of event (mo/day/yr) 4-19-01

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

5. Describe event or problem

GI bleed 4-19-01
also renal failure & exacerbation of CHF

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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.)

Hx renal failure - only has one kidney, GERD, CHF

C. Suspect medication(s)

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

#1 ~~Vioxx 125 mg~~ ASA 81 mg

#2 Naproxen 375 mg

2. Dose, frequency & route used

#1 ~~Vioxx 125 mg qd~~

#2 B10

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

#1 Jan/01

#2 Jan/01

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 (mo/day/yr)

6. model #

catalog #

serial #

lot #

other #

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

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

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

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

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

E. Reporter (see confidentiality section on back)

1. Name & address [redacted] 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.

FDA 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.

CTU 157741

DEC 27 2001

PLEASE TYPE OR USE BLACK INK



3845721-4-00-01

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

Merck Facsimile of FDA Form 3500A Approved by FDA (10/21/93)

Mfr report # WAES 00094052
UF/Dist report #
FDA Use Only

A. Patient information

1. Patient identifier: [redacted]
2. Age at time of event: 79 years
3. Sex: [X] Female
4. Weight: Unk

B. Adverse event or product problem

1. Adverse event and/or Product problem: [X] Adverse event
2. Outcomes attributed to adverse event: [X] hospitalization-initial or prolonged
3. Date of event: 09/03/00
4. Date of this report: 12/19/01

5. Describe event or problem: This is in follow-up to report(s) previously submitted on 09/05/2000; 11/10/2000

A 5-year, Double-Blind, Randomized, Placebo-Controlled Extension Study to Examine the Long-Term Safety and Efficacy of Oral Alendronate in Postmenopausal Osteoporotic Women who Previously Received Alendronate in Conjunction With the Fracture Intervention Trial.

Information has been received concerning a 79 year old female with knee arthritis, arterial blockage, heart palpitations, bladder incontinence and hypercholesterolemia who entered a 5-year, double-blind, randomized, placebo-controlled extension study to examine the long-term safety and efficacy of oral alendronate in conjunction with the Fracture Intervention Trial.

(Continued on Additional Page)

6. Relevant test/laboratory data, including dates: Refer to Additional Page

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.): CONCURRENT CONDITIONS: arterial occlusion; hypercholesterolemia; knee arthritis; palpitation; urinary incontinence

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known): #1 TAB FOSAMAX 10 mg; #2 TAB aspirin 81 mg
2. Dose, frequency & route used: #1 10 mg/DAILY/PO; #2 81 mg/DAILY/PO
3. Therapy dates (if known): #1 05/22/98 - 09/05/00; #2 04/22/98 - 09/05/00

4. Diagnosis for use/indication: #1 osteoporosis; #2 anticoagulant therapy
5. Event abated after use stopped or dose reduced: #1 [X] yes; #2 [X] yes
6. Lot # (if known): #1; #2
7. Exp date (if known): #1; #2
8. Event reappeared after reintroduction: #1 [X] yes; #2 [X] yes
9. NDC # (for product problems only, if known): Unknown

10. Concomitant medical products and therapy dates (excluded treatment of event): b vitamins 04/22/98-Cont; calcium carbonate (w/ vitamin d) 05/07/98-Cont

(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address: Merck Human Health Division, Merck & Co., Inc., P.O. Box 4, West Point, PA 19486-0004
2. Phone Number: (484)344-2415
3. Report source: [X] study
4. Date received by manufacturer: 10/30/00
5. IND, protocol #: 0510002
6. Type of report: [X] 15-day; [X] Follow-up # 2
7. (AINDA # 20560)
8. Mfr report number: WAES 00094052

8. Adverse event term(s): HEMORRHAGIC GASTRIC ULCER

E. Initial reporter

Name, address & phone # [redacted]

9. Health professional? [X] YES
10. Occupation:
11. Initial reporter also sent report to FDA: [X] YES

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

DEC 27 2001

Individual Safety Report



3845721-4-00-02

5. Describe event or problem

enteric coated aspirin, 81 mg daily since 23-APR-1998 for anticoagulant therapy and pentoxifylline, 1200 mg daily since 22-APR-1998 for the treatment of arterial obstruction. Other concomitant therapy included calcium carbonate/cholecalciferol, metoprolol, folic acid, vitamin E, vitamin B, oxybutynin and cerivastatin sodium. On 03-SEP-2000, the patient experienced stomach pain and then passed black tarry stool. On 05-SEP-2000, she was admitted to the hospital and therapy with celecoxib, enteric coated aspirin and pentoxifylline were discontinued. That same day, therapy with alendronate or control was interrupted on the advice of her primary care physician. An esophagogastroduodenoscopy with biopsy was performed on 06-SEP-2000 and the results were a fundic gastric ulcer and a prepyloric antral ulcer with helicobacter pylori gastritis (non-serious AE). At the time of the esophagogastroduodenoscopy, the bleeding had temporarily stopped; however, the final assessment remained as two bleeding gastric ulcers. The patient was maintained initially on liquids and then, slowly advanced on clear liquids and a bland diet. She also received a blood transfusion. No surgery was performed. Subsequently, the patient recovered and was discharged from the hospital on 13-SEP-2000. At this time, the patient had not restarted therapy with alendronate or control. The reporting physician felt that the bleeding gastric ulcers were possibly related to therapy with alendronate or control, celecoxib, enteric coated aspirin, or pentoxifylline. Additional information has been requested. On 07-NOV-2000 this report was unblinded. The patient was found to be on alendronate, 10 mg daily. On 17-DEC-2001, this report was amended. The action taken for primary suspect drug was changed from discontinued to interrupted.

This is a corrected report as amended.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
Esophagogastroduodenoscopy	09/06/00			
Comment: FUNDIC GAST. ULCER/PREPYLOR ANTRAL ULCER				

C. Suspect medication(s)

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

- #3 TAB pentoxifylline 1200 mg
- #4 TAB celecoxib 400 mg

2. Dose, frequency & route used

- #3 1200 mg/DAILY/PO
- #4 400 mg/DAILY/PO

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

- #3 04/22/98 - 09/05/00
- #4 07/13/99 - 09/05/00

4. Diagnosis for use (indication)

- #3 arterial occlusion
- #4 knee arthritis

5. Event abated after use stopped or dose reduced

	YES	NO	N/A	UNK
#3				X
#4				X

6. Lot # (if known)

- #3
- #4

7. Exp date (if known)

- #3
- #4

DEC 27 2001

8. Event reappeared after reintroduction

	YES	NO	N/A	UNK
#3				X
#4				X

C. Suspect medication(s)

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

cerivastatin sodium	12/10/99 - Cont
folic acid	04/22/98 - Cont
metoprolol	04/22/98 - Cont
oxybutynin chloride	09/23/98 - Cont
vitamin e	04/22/98 - Cont

Individual Safety Report



3845721-4-00-03

DEC 27 2001

Individual Safety Report



3846034-7-00-01

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY USA	2. DATE OF BIRTH Day: [redacted] Month: [redacted] Year: [redacted]	2a. AGE 72 yrs	3. SEX F	4-6. REACTION ONSET Day: 08 Month: NOV Year: 2001	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
--------------------------------------	--------------------	--	-------------------	-------------	--	---

7-13. DESCRIBE REACTION(S) (including relevant tests/lab data)
Main event(s): GI BLEED (Code : GI HAEMORRHAGE)
Other term(s): ANAEMIA - WBC ABNORMAL NOS

This case was received from a study investigator via Bristol-Myers Squibb (BMS Case ID 11610847).

A 72-year-old female patient, enrolled in the BMS sponsored MRCVE-IT trial, treated with clopidogrel (Plavix) 75 mg/day -unspecified indication- for 5 weeks experienced severe gastrointestinal bleed.

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG 1 of 2 (include generic name) PLAVIX (CLOPIDOGREL SULFATE) (see attached pages for additional suspect drugs)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
16. ROUTE(S) OF ADMINISTRATION PO	
17. INDICATION(S) FOR USE Unspecified	
18. THERAPY DATES (from/to) From 04-OCT-2001 to continuing	19. THERAPY DURATION NI

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
TREATMENT A (STATIN), Dates: From 04-OCT-2001 to 06-NOV-2001, Duration: 4 weeks 6 days, Dose: UNK, Route: UNK
TREATMENT B (GATIFLOXACIN/PLACEBO) (GATIFLOXACINE), Dates: From 31-OCT-2001 to 06-NOV-2001, Duration: 1 week 6 days, Dose: UNK, Route: UNK *

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc)
History: Unknown
Concomitant disease(s): Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER SANOPI-SYNTHELABO 31 Av P. Vaillant Couturier BP 110 92225 Bagneux Cedex France	24c. MFR CONTROL NO. N133455
24b. DATE RECEIVED BY MANUFACTURER 03-DEC-2001	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL
DATE OF THIS REPORT 21-DEC-2001	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP

NI - No information available at this time UNK - Information Unknown

* Item completed on continuation page(s)

DSS

DEC 27 2001

DEC 28 2001



3846034-7-00-02

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET*			8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7-13. DESCRIBE REACTION(S) (including relevant testis/ab data):										<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG 2 of 2 (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
ASA (ASPIRIN)		<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
325 mg	UNK	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
17. INDICATION(S) FOR USE		
NI		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	
From 30-SEP-2001 to continuing	NI	

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER	
24b. MFR CONTROL NO N133455	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP

NI - No information available at this time UNK - information unknown

* Item completed on continuation page(s)

DSS

DEC 27 2001

DEC 28 2001

INDIVIDUAL Safety Report



3846034-7-00-03

CIOMS FORM

CONTINUES PREVIOUS PAGE	1. PATIENT INITIALS (first,last) 	24b. MFR CONTROL NO N133455
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7 - 13 DESCRIBE REACTION(S) (including relevant test/lab data)

[continuation:] On 30-Sep-2001, the patient was started on aspirin. On 04-Oct-2001, the patient was started on clopidogrel and treatment A (statin). Treatment B was started about 4 weeks after.

On 05-Nov-2001 treatments A and B were discontinued.

On 38-Nov-2001 the patient experienced severe gastrointestinal bleed for which she was hospitalized and a gastroscopy was performed. On admission, laboratory investigations revealed anemia. The oesophagus and stomach were normal on four retroflex views. Two ulcers, one large approximately 1 cm in size and one of 0.5 cm in size were found in the duodenum. The larger one had a red spot consistent with a visible vessel. There was no active bleeding at this point. Surgeon coagulated both ulcers as there were two "hemocystic" lesions. There were no bleeding.

The reporter think that the patient had bled from duodenal ulcers. Clopidogrel and aspirin were both considered as suspect drugs by the investigator. Relationship to Treatments A and B were listed as not likely.

Outcome: unknown

Additional information received on 13-dec-2001, revealed that on admission, anemia (Hb = 10.7 g/dL). The patient also developed increased white blood cell count (12,400/mm3, however platelets were within normal range.

Outcome: unknown

MAH comment: Based on chronology, the role of clopidogrel cannot be ruled out. Increased white blood count can be associated with hemorrhage.

Relevant tests:

08-Nov-2001
 Hb 10.7 g/dl
 Ect 0.33 IU
 Platelets 378 x 10E9/L
 WBC 12.4 x 10E9/L
 INP 1.02

Corrective treatment: Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

[continuation:] METOPROLOL, Dates: From 30-SEP-2001 to continuing, Duration: NI, Dose: 50 mg, Route: UNK

RAMIPRIL, Dates: From 30-SEP-2001 to continuing, Duration: NI, Dose: 2.5 mg, Route: UNK

METFORMIN, Dates: From 30-SEP-2001 to continuing, Duration: NI, Dose: 500 mg, Route: UNK

ZANFAC (RANITIDINE HYDROCHLORIDE), Dates: From 01-OCT-2001 to continuing, Duration: NI, Dose: 300 mg, Route: UNK

Comments: All concomitant drugs started at least four weeks before ADR onset except for treatment B which was started 8 days before ADR onset.

All concomitant drugs were continued except for treatment A and B which were discontinued 2 days before ADR onset.

DSS

DEC 28 2001

DEC 27 2001

CERT# 0794 7822

MedWatch

The FDA Medical Products Reporting Program

Merck Human Health Division

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

Merck Facsimile of FDA Form 3500A Approved by FDA (10/21/93)

Mfr report # WAES 01062374
LFI/Dist report #
FDA Use Only

Page 1 0093436

NO ATTACHMENT

A. Patient Information
1. Patient identifier
2. Age at time of event: 80 years
3. Sex: Male
4. Weight: Unk
B. Adverse event or product problem
1. Adverse event and/or Product problem
2. Outcomes attributed to adverse event
3. Date of event: 06/24/01
4. Date of this report: 07/17/01
5. Describe event or problem
Information has been received from a physician and his office nurse concerning a debilitated 80 year old male nursing home patient with contact dermatitis, a hip contusion, pneumonia, and no past medical history of gastrointestinal complaints who on 16-MAR-2001, was placed on therapy with rofecoxib, 25 mg tablet (previously reported as 12.5 mg by the physician), once a day for the treatment of arthritis pain in his shoulder. Concomitant therapy included aspirin, 81 mg daily (previously reported as 325 mg daily by the physician) (duration and indication not reported) (secondary suspect). Other concomitant therapy included atenolol and cephalixin (KEFLEX). On 24-JUN-2001, the patient developed a severe gastrointestinal (GI) bleed secondary to a duodenal ulcer and was hospitalized. On 25-JUN-2001, therapy with rofecoxib and aspirin was discontinued. The GI bleed required four units of blood. The patient subsequently completely recovered and after four days was
(Continued on Additional Page)
6. Relevant tests/laboratory data, including dates
Unknown
7. Other relevant history, including preexisting medical conditions
(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
CONCURRENT CONDITIONS: contact dermatitis; contusion; debility; pneumonia

C. Suspect medication(s)
1. Name (give labeled strength & mfr/labeler, if known)
#1 TAB VIOXX 25 mg
#2 aspirin 81 mg
2. Dose, frequency & route used
#1 25 mg/DAILY/PO
#2 81 mg/DAILY/PO
3. Therapy dates (from/to; if unknown, give duration)
#1 03/16/01 - 06/25/01
#2 Unk - 06/25/01
4. Diagnosis for use (indication)
#1 arthritis pain
#2 Unknown
5. Event abated after use stopped or dose reduced.
#1 [X] yes [] no [] N/A [] unk
#2 [X] yes [] no [] N/A [] unk
6. Lot # (# known)
#1
#2
7. Exp date (if known)
#1
#2
8. Event reappeared after reintroduction.
#1 [] yes [] no [] N/A [] unk [X]
#2 [] yes [] no [] N/A [] unk [X]
9. NDC # - for product problems only (# known)
Unknown
10. Concomitant medical products and therapy dates (exclude treatment of event)
KEFLEX Unk -Unk
atenolol Unk -Unk

G. All manufacturers
1. Contact office - name/address
Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004
ATTN: Worldwide Product Safety
2. Phone Number
(610)397-2416
3. Report source (check all that apply)
[] foreign
[] study
[] literature
[] consumer
[X] health professional
[] user facility
[X] company representative
[] distributor
[] other
4. Date received by manufacturer (m/d/yyyy)
07/10/01
5. (ANDA # 21042)
IND #
PLA #
pre-1938 [] yes [] no
OTC product [] yes [] no
9. Mfr. report number
WAES 01062374

8. Adverse event term(s)
HEMORRHAGIC DUODENAL ULCER

E. Initial reporter
1. Name, address & phone #
[Redacted]
DSS
2. Health professional?
[X] YES [] NO
3. Occupation
M.D.
4. Initial reporter also sent report to FDA.
[] yes [] no [X] unk

Submission of a report does not constitute an admission that...



JUL 19 2001

B. Adverse event or product problem

5. Describe event or problem

discharged back to the nursing home. According to the nurse, the GI bleed was thought to be related to therapy with rofecoxib and aspirin.

The GI bleed secondary to a duodenal ulcer was considered to be immediately life threatening and an other important medical event. No further information is available.

DSS

07/20/2001



JUL 19 2001

B. Adverse event or product problem

5. Describe event or problem

hemoglobin (MCH) was 34, platelet count was 326000, and bleeding time was greater than 15 minutes. An esophagogastroduodenoscopy (EGD) was performed which revealed grade 4 esophagitis, duodenal ulcers, and one post-duodenal ulcer. The patient was placed on therapy with unspecified proton pump inhibitors. On 13-FEB-2001 hemoglobin was stable at 11.6 and the patient was discharged from the hospital. The report indicated that the patient was to remain on "life long" therapy with proton pump inhibitors, but indicated that the symptoms abated following discontinuation of rofecoxib. Aspirin was considered a secondary suspect medication.

Additional information has been received from the pharmacist who originally reported the information concerning the 63 year old, white, male patient. Additional concurrent conditions included chronic obstructive pulmonary disease and concomitant therapy included indomethacin (MSD). The pharmacist clarified that on approximately 14-JAN-2001 the patient was placed on therapy with rofecoxib, 50 mg tablet, once daily for the treatment of pain. Aspirin therapy was for the treatment of rheumatic fever. On 14-FEB-2001 the patient presented to the emergency room with red blood in his stool and dark black stools since the day prior. The patient also complained of vomiting dark, bloody chunks on the morning of 14-FEB-2001. Aspirin therapy was discontinued on 16-FEB-2001. Additional follow up was received from a completed questionnaire. The source of the bleeding was identified as the grade IV/erosive esophagitis and the duodenal ulcer. No tests were completed for Helicobacter Pylori.

The reporting pharmacist considered the gastrointestinal bleeding, duodenal ulcer, gastrointestinal ulcer, and erosive esophagitis to be Other Important Medical Events. Additional information is not expected.

This report was filed with the FDA. The CTU number is 141198.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

<u>Tests</u>	<u>Date</u>	<u>Value</u>	<u>Unit</u>	<u>Normal Range</u>
esophagogastroduodenoscopy	02/14/01			
Comment: grade 4 esophagitis, duodenal ulcers, one post-duodenal ulcer				

LABORATORY RESULTS

<u>Tests</u>	<u>Date</u>	<u>Value</u>	<u>Unit</u>	<u>Normal Range</u>
APTT	02/14/01	27.7		
INR	02/14/01	0.95		
hemoglobin	02/14/01	16.5		
platelet count	02/14/01	326000		
bleeding time	02/14/01	>15 min.		
mean corpuscular hemoglobin	02/14/01	34		
mean corpuscular volume	02/14/01	102.5		
hemoglobin	02/18/01	11.6		

DSS

02/20/2001



3762870-3-00-02

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