Individual Safety Report

3665530-9-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ealth professionals of adverse
vents and product problems

Page ___ of ___

Form Approved OMB No. 0910-0291 Expires:12
See OMB statement on r

FDA Use Only

Triage unit sequence # 137622

A. Patient information

1. Patient identifier: [redacted]6017 In confidence
2. Age at time of event: 73 or Date of birth:
3. Sex: ☐ female ☑ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr)
   - ☐ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 9-2-00
4. Date of this report (mo/day/yr):
5. Describe event or problem

GI BLEED

PATIENT INSTRUCTED NOT TO TAKE NAPROXEN WHILE TAKING INDOMETHACIN, BUT APPARENTLY DID SO.

6. Relevant tests/laboratory data, including dates

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

CTG
137622

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 INDOMETHACIN
   - #2 NAPROXEN
2. Dose, frequency & route used
   - #1
   - #2
3. Therapy dates (if unknown, give duratio from/to (or best estimate)
   - #1 5-12-00 →
   - #2 11-4-97 →
4. Diagnosis for use (indication)
   - #1 ARTHRITIS
   - #2
5. Event abated after use stopped or dose reduc
   - #1 ☑ yes ☐ no ☐ does app
   - #2 ☐ yes ☐ no ☐ does app
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☑ does app
   - #2 ☐ yes ☐ no ☑ does app
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

EPOGEN, DIAMOX, LOVASTATIN, TEMAZEPIN, AMITRIPTYLINE, ASPIRIN, BACLOFEN, CLOPIDOGREL, PILOCARPINE, FLUOXETINE, FOSINOPRIL, ISOSORBIDE, PILEVACID

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health profession
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mo/day/yr)
6. model # DSS
   catalog #
   serial # FEB 15 2001
   lot #
   other #
7. If implanted, give da (mo/day/yr)
8. If explanted, give da (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

OVERTON BROOKS VA MEDICAL CENTER
510 EAST STONER AVENUE
SHREVEPORT, LOUISIANA 71101-4295
(318)-424-6001

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

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

FDA Form 3500 (6/93)

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

Individual Safety Report

3666035-1-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting health professionals of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 12/31/5
See OMB statement on revers

FDA Use Only

Triage unit sequence # 137656

A. Patient information

1. Patient identifier: 3748 (In confidence)
2. Age at time of event: 70 or Date of birth:
3. Sex: ☐ female ☑ male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr)
   - ☐ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 5-5-00
4. Date of this report (mo/day/yr)
5. Describe event or problem

GI BLEED
(BLACK TARRY STOOLS)

NAPROXEN DCed

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.)

CTU137656

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 NAPROXEN
   #2
2. Dose, frequency & route used
   #1 N/A
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 N/A (NOT ON FROM VAMC)
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☑ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

LANSOPRAZOLE

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)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   OVERTON BROOKS VA MEDICAL CENTER
   510 EAST STONER AVENUE
   SHREVEPORT, LOUISIANA 71101-4295
   (318)-424-6001
2. Health professional? ☑ 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. ☒

DSS
FEB 15 2001

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

3669314-7-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page 1 of 1

Form Approved: OMB No. 0910-0291 Expires: 12/31/2 See OMB statement on reverse

FDA Use Only (Internal) Image sent sequence # 138205

A. Patient information

1. Patient identifier: XX (in confidence)
2. Age at time of event: 75y or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply): [ ] death (mm/dd/yyyy) [ ] life-threatening [X] hospitalization – initial or prolonged [ ] disability [ ] congenital anomaly [ ] required intervention to prevent permanent impairment/damage [ ] other:
3. Date of event (mm/dd/yyyy): 10-31-00
4. Date of this report (mm/dd/yyyy): 2-23-01
5. Describe event or problem

GASTROINTESTINAL BLEED: MELENA. Patient w/ H/O PUD taking lansoprazole, came to hospital c/o black stools & fatigue. She has been taking naproxen x years for hip pain. Recently she began taking 2 regular aspirin QD for headaches. C/O dizziness x 3 months; becoming progressively paler. In Emer Room: Hbg 5.6 transfused w/ 2 units PRBC. EGD showed 12-13mm deep central ulcer, clean based duodenal ulcer. Impression: H/O PUD + H. pylori w/ slow bleed x 3 months w/ recent increase likely to aspirin and chronic naproxen use. When discharged home H/H stable and asymptomatic.

DISCHARGED 2 DAYS P ADMISSION

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.)

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CTV138205

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 NAPROXEN
   #2 ASPIRIN
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) (month for 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)
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 FEB 23 2001

4. Operator of device: [ ] health professional [ ] lay user/patient [ ] other:
5. Expiration date (mm/dd/yyyy)
6. model # / catalog # / serial # / lot # / other #

MEDWATCH CTU

7. If implanted, give date (mm/dd/yyyy)
8. If explanted, give date (mm/dd/yyyy)
9. Device available for evaluation? (Do not send 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, address & phone #: [redacted] DSS [redacted] MED CTR [redacted] ST [redacted]

RECEIVED FEB 26 2001

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

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.

WYETH

3699463-9-00-01

MEDWATCH

AL PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ6622130MAY2000

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: [redacted] n confidence
2. Age at time of event: or 67Yr; Date of Birth: [redacted]
3. Sex: [ ] female [X] male
4. Weight: 215 lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event [ ] Product problem (e.g., defects/malfunctions)

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

3. Date of event (mo/day/yr): 00/00/1999
4. Date of this report (mo/day/yr): 03/28/2001

5. Describe event or problem

Information was received on 26-MAY-2000 from a physician via Merck & Co., Inc. and on 12-JUN-2000 from a registered nurse via Covance regarding a 67-year-old white male patient. The patient's concurrent illnesses include Arthritis NOS. Additional medical history was not provided. Therapy with LODINE CAPSULE (etodolac capsule) for Arthritis NOS began in 1999 (therapy dates not specified). The dose regimen included: two, 500mg doses, every day. Additional suspect medication included ACETYLSALICYLIC ACID and NAPROXEN SODIUM. The patient experienced stomach bleeding (Gastrointestinal haemorrhage NOS) while taking LODINE CAPSULE and ACETYLSALICYLIC ACID (Drug interaction NOS). He was subsequently hospitalized for two days and nights. The patient 'was fine' at the time of discharge and continued LODINE CAPSULE therapy (ACETYLSALICYLIC ACID was discontinued). In follow-up information received on 12-JUN-2000, the nurse indicated the patient was taking LODINE CAPSULE (etodolac capsule) concomitantly with

(cont'd)

6. Relevant tests/laboratory data, including dates

None Provided.

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

CONCURRENT CONDITIONS:

Arthritis NOS

C. Suspect medication(s)

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

#1 LODINE (ETODOLAC, Capsule)

#2 ACETYLSALICYLIC ACID (ACETYLSALICYLIC ACID,)

(cont'd)

2. Dose, frequency & route used
- #1 500 mg 2x per 1 Day, Oral
- #2 Dose not specified, Oral

3. Therapy dates (if unknown, give duration)
- #1 00/00/1999 to UNK
- #2 00/00/1999 to UNK

4. Diagnosis for use (indication)
- #1 Arthritis NOS
- #2 UNK

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

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

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

8. Event reappeared after reintroduction
- #1 [ ] yes [X] no [ ] doesn't apply
- #2 [ ] yes [ ] no [X] doesn't apply

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

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

UNK

G. All manufacturers

1. Contact office – name/address

WYETH LABS (RA)
240 N Radnor-Chester
St. Davids, PA 19087

Jill Robinson

2. Phone number: 6109024647

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

4. Date received by manufacturer (mo/day/yr): 05/26/2000

5. (A)NDA 18-922; IND #; PLA #; pre-1938 [ ] yes; OTC product [ ] yes

6. If IND, protocol #

7. Type of report
- [ ] 5-day [ ] 15-day
- [ ] 10-day [X] periodic
- [X] initial [ ] follow-up #

8. Adverse event term(s)

Gastrointestinal haemorrhage NOS

Drug interaction NOS

9. Mfr. report number: HQ6622130MAY2000

E. Initial reporter

1. Name & address — phone # 610-397-2416

Hostelley, Linda S., Dr.
Merck & Co., Inc.
PO Box 4
West Point, PA 19486, US

2. Health professional? [X] yes [ ] no

3. Occupation: Physician

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk

FDA Form 3500A (facsimile)

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

WYETH
WAYERST Safety Report

3699463-9-00-02

MEDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ6622130MAY2000

UF/D st report #

FDA Use Only

Box B.5 - Describe event or problem (Continuation)

Aleve (NAPROXEN SODIUM). Additional information has been requested.

Box C - Suspect medication(s) (Continuation)

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

3.1 NAPROXEN SODIUM (NAPROXEN SODIUM,)

2. Dose, frequency & route used

3.1 1 Tablet 2x per 1 Day, Oral

3. Therapy dates (if unknown, give duration)

3.1 05/31/1999 to 05/31/1999

4. Diagnosis for use (indication)

3.1 Arthritis NOS

5. Event abated after use stopped or dose reduced

3.1 DOESN'T APPLY

6. Lot # (if known)

3.1

7. Exp date (if known)

8. Event reappeared after reintroduction

3.1 DOESN'T APPLY

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

Individual Safety Report

3708839-2-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/01
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 141749

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: or Date of birth: [redacted]
3. Sex: [ ] female [✓] male
4. Weight: lbs or 86.5 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): 04/14/2001
4. Date of this report (mm/dd/yyyy): 04/20/2001
5. Describe event or problem

GI Bleed, Dark stools

6. Relevant tests/laboratory data, including dates

EGP=Duodenal ulcer

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

R knee injury, Naproxen x 3 weeks, Vioxx x 2 weeks now

CJV147749

APR 20 2001

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
   - #1 Naproxen
   - #2 Vioxx
2. Dose/Frequency/Route used
   - #1
   - #2
3. Therapy dates (if unknown, give duration) From To (or best estimate)
   - #1
   - #2
4. Diagnosis for use (separate indications with commas)
   - #1 knee pain
   - #2 knee pain
5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [ ] no [✓] doesn't apply
   - #2 [ ] yes [ ] no [✓] doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 [ ] yes [ ] no [ ] doesn't apply
   - #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
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)

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E. Reporter (see confidentiality section on back)

1. Name
   phone # [redacted]
   [redacted] Hospital, [redacted] Ave. Inpatient Pharmacy
   [redacted]
   United States [redacted]
2. Health professional? [✓] yes [ ] no
3. Occupation: Other Health Professional
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
APR 23 2001

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.

MEDWATCH
Individual Safety Report

3709248-2-00-01

VOLUNTARY reporting
professionals of adverse
and product problems

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

FDA Use Only
Triage Unit Log/Seq No: 194814

A. Patient information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted]2377 In confidence	45 or Date of birth:	☐ female ☒ male	lbs or 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 (mm/dd/yy)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mm/dd/yy): 11/28/00
4. Date of this report (mm/dd/yy): 4/23/01
5. Describe event or problem

Pt had been taking NSAIDS chronically for his back pain. He was admitted for observation + the naproxen was D/c'd. He'd been having dark stools, abdominal pain + hematemesis. By the next day, he had no further heme⊖ stools. his HGB remained stable, his abdominal pain improved, + an NG lavage was⊖.

6. Relevant tests/laboratory data, including dates

11/28/00
Hg = 14.6
HCT = 42.3

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

GERD, Depression, HTN
CAD
angioplasty, Bipdar
DJD
CTU94814 etoh dependence

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Naproxen 250mg
   - #2 (Before naproxen, he took Motrin⊖
2. Dose, frequency & route used
   - #1 250mg PoTID
   - #2 800mg TID PRN
3. Therapy dates (if unknown, give duration) (mm/dd/yy)
   - #1 ~1 week
   - #2 >1 year
4. Diagnosis for use (indication)
   - #1 Chronic low back pain
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☒ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☒ doesn't apply
   - #2 ☐ yes ☐ no ☒ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

nicotine patch, NTG
Trazodone, lisinopril
Paxil, Prevacid

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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APR 24 2001
MEDWATCH CTU

4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mm/dd/yy)
6. Model #
7. If implanted, give date (mm/dd/yy)
8. If explanted, give date (mm/dd/yy)
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on (mm/dd/yy)
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
   VA Med Center 119
   2200 Gage TOPEKA, KS 66622 [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: RPh
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

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

DSS

APR 24 2001

Individual Safety Report

3720099-5-00-01

MEDWATCH

THE F[illegible] MEDICAL PRODUCTS REPORTING PROGRAM

Bayer Corporation

Approved by FDA on 3/22/94

Domain Facsimile

Mfr report # 200110245BCC

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: 67 yrs or Date of birth: [redacted]
3. Sex: [illegible] female [illegible] male
4. Weight: 187 lbs or [illegible] kgs

B. Adverse event or product problem

1. [illegible] Adverse event and/or Product problem (e.g. defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [illegible]th
   - [illegible] threatening
   - [illegible]pitalization - initial or prolonged
   - disability
   - congenital anomaly
   - required intervention to prevent permanent impairment/damage
   - other: Med. Important
3. Date of event (mo/day/yr): 22-APR-2001
4. Date of this report (mo/day/yr): 07-MAY-2001
5. Description of event or problem

[illegible]SE BLEED
Spitting up blood

[illegible]obal Narrative:
[illegible]is initial spontaneous report was provided [illegible] a consumer, via a Consumer Care [illegible]presentative, in the United States on 23-[illegible]R-2001.

[illegible] 68 year-old female consumer (race and [illegible]eight unknown) was treated with ALEVE® [illegible]aplets-24s (naproxen sodium) for the [illegible]dication of general pain relief from [illegible]uises at a dose of 1 caplet daily from 13-[illegible]R-2001 to 22-APR-2001. On 22-APR-2001, she [illegible]perienced SEVERE NOSE BLEED (stop date [illegible]known) with the symptom of spitting up *

6. Relevant tests/laboratory data, including dates

[illegible]ne reported

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

[illegible]ncomitant disease(s): Left ethmoid sinus [illegible]ncer
[illegible]ce: UNK
[illegible]egnant: UNK

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 ALEVE
   #2
2. Dose, frequency & route used
   #1 1 daily ORAL
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 13-APR-2001 to 22-APR-2001
   #2
4. Diagnosis for use (indication)
   #1 General Pain Relief
   #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 UNK
7. Exp. date (if known)
   #1 NI
   #2
8. Event reappeared after reintroduction
   #1 [ ] yes [ ] no [ ] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # - for product problems only (if known)
   #1 NI #2
10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: Thyroid pill Dates:
Name: Centrum Multivitamin Dates:
Name: NASAL SALINE Dates:

G. All manufacturers

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

Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516-4175

2. Phone number: 888-765-3203
3. Report source (check all that apply)
   - [ ] foreign
   - [ ] study
   - [ ] literature
   - [X] consumer
   - [ ] health professional
   - [ ] user facility
   - [ ] company representative
   - [ ] distributor
   - [X] other: *
4. Date received by manufacturer (mo/day/yr): 23-APR-2001
5. (A)NDA # 20-204
   IND #
   PLA #
   pre-1938 [ ] yes
   OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply)
   - [ ] 5-day [X] 15-day
   - [ ] 10-day [ ] periodic
   - [X] Initial [ ] follow-up #
8. Adverse event term(s)

MAY 0 8 2001

9. Mfr. report number: 200110245BCC

E. Initial reporter

1. Name, address & phone #

Ms. [redacted]
[redacted] St
[redacted] US
Phone: [redacted]

2. Health professional? [ ] yes [ ] no
3. Occupation: NI
4. Initial reporter also sent report to FDA? [ ] yes [ ] no [X] unk

MAY 0 8 2001

FDA

Domain Facsimile of FDA Form 3500

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.

BAYER CORP. DRUG RECD MAY 0 8 2001 CDR NUTRITION AND RESEARCH

Individual Safety Report

3720099-5-00-02

Bayer Corporation

MED WATCH

A.1. Patient identifier

G.9. Mfr. report number

200110245BCC

B.5. Describe event or problem

[continuation:] blood. The event is considered serious (important medical event). The consumer also spit up a little dark purple blood on 23-APR-2001. She plans to see her doctor for evaluation of these symptoms.

Concomitant medications include SALINE SOLUTION (sodium chloride) use in nose since 1992, CENTRUM MULTIVITAMIN (multiple vitamins) and a THYROID PILL NOS (therapy dates and dosing regimens unknown). The consumer has a relevant history of left ethmoid sinus cancer since 1992.

For the suspect drug ALEVE (naproxen sodium), NOSE BLEED with spitting up blood: Rechallenge, dechallange, action taken and outcome of the event is unknown. No other labs, tests or history reported.

Global Comment:
SEVERE NOSE BLEED with symptom of spitting up blood is not listed in the U.S. Product Information for Aleve Caplets (naproxen sodium). Based on the information received a causal relationship between the event and naproxen sodium can be excluded. This is supported by the patient's cancer of the left ethmoid sinus, which is the source of the bleeding.

G.3. Report source (other)

BAYER CONSUMER CARE USA

MAY 0 8 2001

DS3

MAY 0 9 2001

Individual Safety Report

3721065-6-00-01

...ties, distributors and manufacturers for MANDATORY reporting.

APPROVED BY FDA ON 03/06/98

Mfr report # 237773

UF/Dist. report #

FDA Use only

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 65 YEARS or Date of birth
3. Sex: [X] female [ ] male
4. Weight: 170 lbs or 77.1 kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply): [ ] death (mo/day/yr) / / [ ] life threatening [ ] hospitalization initial or prolonge [ ] disability [ ] congenital anomaly [ ] required intervention to prevent permanent impairment/damage [X] other NON-SERIOUS
3. Date of event (mo/day/yr): / / 1993 E
4. Date of this report (mo/day/yr): MAY / 10 / 2001
5. Describe event or problem

THIS SPONTANEOUS CASE WAS REPORTED BY THE 65-YEAR-OLD FEMALE PATIENT WHO EXPERIENCED GASTRO-OESOPHAGEAL REFLUX DISEASE. ABDOMINAL PAIN AND RECTAL BLEEDING DURING THE USE OF NAPROSYN (NAPROXEN) FOR ARTHRITIS (TYPE UNSPECIFIED).

THE PATIENT IS A NON-DRINKER, NON-SMOKER WITH A DRUG ALLERGY TO MOTRIN (IBUPROFEN). THE PATIENT HAS A MEDICAL HISTORY OF HYPERTENSION.

1983 (EST.): ORAL NAPROSYN THERAPY WAS INITIATED BID AT A MAXIMUM DOSE (NOT FURTHER SPECIFIED). 1993 (EST.), THE PATIENT STARTED TO EXPERIENCE RECTAL BLEEDING AND ABDOMINAL DISCOMFORT. THE PATIENT CONSULTED HER PHYSICIAN AND WAS DIAGNOSED WITH RECTAL BLEEDING AND GASTRO-OESOPHAGEAL REFLUX DISEASE. NAPROSYN WAS DISCONTINUED. APPROXIMATELY 3 WEEKS AFTER THE DISCONTINUATION OF NAPROSYN THE RECTAL BLEEDING AND GER RESOLVED. DATE UNKNOWN. THE ABDOMINAL DISCOMFORT RESOLVED.

CONTINUED

6. Relevant tests/laboratory data, including dates

UNK

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

Medical History Terms
DRUG ALLERGY
HYPERTENSION

Medical History Text
THE PATIENT IS A NON-DRINKER, NON-SMOKER WITH A DRUG ALLERGY TO MOTRIN (IBUPROFEN).

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler if known)
#1 NAPROSYN (NAPROXEN)
#2 NA
2. Dose, frequency & route
#1 2 per DAY ORAL
#2 NA
3. Therapy dates (if unk, give duration) from/to (or best estimate)
#1 15-JUN-1983 E / 15-JUN-1993 E
#2 NA
4. Diagnosis for use (indication)
#1 ARTHRITIS
#2 NA
5. Event abated after use stopped or dose reduced
#1 [X] yes [ ] no [ ] doesn't apply
#2 [ ] yes [ ] no [X] doesn't apply
6. Lot # (if known)
#1 UNK
#2 NA
7. Exp. date (if known)
#1 UNK
#2 NA
8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [X] 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)
HYDROCHLOORTHIAZIDE 15-JUN-1980 E / 15-JUN-1995 E
(HYDROCHLOROTHIAZIDE)

G. All manufacturers

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

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

2. Phone Number
(973) 562-3523

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

CONTINUED

4. Date received by manufacturer (mo/day/yr)
MAY / 31 / 2000

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

6. If IND, protocol #
NA

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

8. Adverse event term(s)
GASTRO-OESOPHAGEAL REFLUX DISEASE
+++
ABDOMINAL PAIN
RECTAL BLEEDING

9. MFR. report number
237773

+++ adverse event that generated submission

E. Initial reporter

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

CONTINUED

2. Health professional? [ ] yes [X] no
3. Occupation
N/A
4. Initial reporter also sent report to FDA [ ] yes [ ] no [X] 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.

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

MAY 10 2001

B.5. Describe event or problem - continued

AS OF 1 JUN 00 ALL EVENTS HAD REMAINED RESOLVED.
THE PATIENT STATED THAT SHE HAD EXPERIENCED GASTRO-OESOPHAGEAL DISEASE AND RECTAL BLEEDING WHILE ON MOTRIN (DATES NOT SPECIFIED).

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

PHONE: [redacted]

G.3. Report Source (other:) - continued

PHARMACEUTICAL COMPANY

Individual Safety Report

3726467-X-00-01

use by user-facilities, ors and manufacturers for NDATORY reporting.

APPROVED BY FDA ON 03/06/93

Mfr report # 260195

UF/Dist. 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: 40 YEARS or Date of birth: [redacted]

3. Sex: [ ] female [X] male

4. Weight: UNK lbs or kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply)
[ ] death (mo/day/yr) / /
[ ] life threatening
[ ] hospitalization initial or prolonge
[ ] disability
[ ] congenital anomaly
[ ] required intervention to prevent permanent impairment/damage
[X] other: MEDICALLY SIGNIFICANT

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

4. Date of this report (mo/day/yr) MAY / 18 / 2001

5. Describe event or problem

THIS SPONTANEOUS CASE, RECEIVED VIA KNOLL PHARMACEUTICAL COMPANY (USA) AND REPORTED BY THE PATIENT. CONCERNS A 40 YEAR OLD MALE PATIENT WHO EXPERIENCED AN UNSPECIFIED DISORDER OF THE SHOULDER JOINT REGION, INCREASED BLOOD SUGAR AND STOMACH HAEMORRHAGE DURING/FOLLOWING THE USE OF NAPROSYN (NAPROXEN) FOR AN UNSPECIFIED INDICATION AND VICOPROFEN (HYDROCODONE/IBUPROFEN) FOR PAIN AND IMFLAMMATION.

THE PATIENT HAS A HISTORY OF ORTHOPAEDIC SURGERY ON HIS RIGHT SHOULDER (2000) AND WAS DIAGNOSED WITH DIABETES SEVERAL YEARS AGO. HE WAS TAKING DAYPRO (OXAPROZIN), VIOXX (ROFECOXIB) AND IBUPROFEN CONCOMITANTLY.
UNKNOWN DATE (SEVERAL YEARS AGO): THE PATIENT WAS DIAGNOSED WITH DIABETES, AT WHICH TIME HIS BLOOD SUGARS WERE OVER 200.
UNKNOWN DATE: THE PATIENT COMMENCED NAPROSYN THERAPY (DOSE AND REGIMEN UNKNOWN).
NOV 2000 (APPROX): THE PATIENT COMMENCED AND VICOPROFEN (HYDROCODONE/IBUPROFEN) THERAPY 1

CONTINUED

6. Relevant tests/laboratory data, including dates

BLOOD GLUCOSE
2000 E
LAB RESULT: 140-160
NO UNITS PROVIDED.

BLOOD GLUCOSE
FEB-2001 E

CONTINUED

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

Medical History Terms
SURGERY 2000 E
DIABETES

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 NAPROSYN SUSPENSION (NAPROXEN)
#2 VICOPROFEN (HYDROCODONE BITARTRATE/IBUPROFEN)

2. Dose, frequency & route
#1 ORAL
#2 1 DOSE FORM 1 per 6 HOUR ORAL

3. Therapy dates (if unk give duration) from/to (or best estimate)
#1 UNK
#2 15-NOV-2000 E / UNK

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

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

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

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

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [X] 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)
DAYPRO UNK
(OXAPROZIN)

VIOXX UNK
(ROFECOXIB)

CONTINUED

G. All manufacturers

1. Contact Office-name/address
GLOBAL DEVELOPMENT
HOFFMANN-LA ROCHE INC.
340 KINGSLAND STREET
NUTLEY, NJ 07110-1199

2. Phone Number
973) 562-3523

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

4. Date received by manufacturer
MAY / 7 / 2001

5. (A)NDA# 18-965
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #
NA

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

8. Adverse event term(s)
UNSPEC DISORDER JOINT OF SHOULDER REGION +++
BLOOD SUGAR INCREASED
-SUGAR IN URINE
STOMACH HEMORRHAGE

+++ adverse event that generated submission - comanifestation

9. MFR. report number
260195

CONTINUED

E. Initial reporter

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

2. Health professional?
[ ] yes [X] no

3. Occupation
N/A

4. Initial reporter also sent report to FDA
[ ] yes [ ] no [X] 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.

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

B.5. Describe event or problem - continued

TABLET EVERY 6-8 HOURS, PO.
2000 (EXACT DATES UNKNOWN): THE PATIENT'S BLOOD SUGARS WERE BETWEEN 140-160. THE PATIENT EXPERIENCED STOMACH PROBLEMS AND STOMACH BLEEDING. HE STATED THAT VICOPROFEN WAS THE ONLY MEDICATION THAT DID NOT CAUSE THESE PROBLEMS.
UNKNOWN DATE: THE PATIENT STOPPED NAPROSYN THERAPY.
FEB 2001 (APPROX): THE PATIENT STATED THAT HE HAD PREVIOUSLY BEEN ABLE TO KEEP HIS BLOOD SUGARS UNDER CONTROL WITH DIET. IN FEBRUARY, HIS FASTING BLOOD SUGAR WAS NOTED BY THE DOCTOR TO BE 200 AND 215. THE PATIENT'S URINE WAS POSITIVE FOR SUGAR.
MARCH 2001 (APPROX): THE PATIENT BEGAN CHECKING HIS FASTING BLOOD SUGAR DAILY WITH A HOME KIT. HIS LEVELS WERE ALWAYS OVER 200 AND AS HIGH AS 372.
02 MAY 2001: THE PATIENT STATED HE HAD RECENTLY ATTENDED DIABETES CLASSES AND WAS NOW MORE DILIGENT WITH HIS DIET. HE WAS AWARE THAT HE SHOULD BE EXERCISING, BUT THIS WAS DIFFICULT DUE TO THE DEVELOPMENT OF REFLEX SHOULDER DYSTROPHY. HIS MOST RECENT BLOOD SUGAR LEVELS WERE AROUND 200. THE PATIENT STATED THAT HE FELT THAT STRESS HAD CONTRIBUTED TO HIS EARLIER INCREASE IN BLOOD SUGAR LEVELS.
NO UNITS WERE PROVIDED UNLESS SPECIFIED.
THE PATIENT STATED THAT HE USED TO TAKE DAYPRO, NAPROSYN, VIOXX AND HIGHER DOSES OF IBUPROFEN BUT THEY ALL CAUSED STOMACH PROBLEMS AND STOMACH BLEEDING.
AT THE TIME OF THE REPORT, THERE WAS INSUFFICIENT INFORMATION TO ASCERTAIN THE OUTCOME OF THE UNSPECIFIED DISORDER OF THE SHOULDER JOINT REGION AND STOMACH HAEMORRHAGE OR WHETHER THE VICOPROFEN WAS CONTINUING.
THE COMPANY CONSIDERED THE UNSPECIFIED DISORDER OF THE SHOULDER JOINT REGION, INCREASED BLOOD SUGAR AND STOMACH HAEMORRHAGE TO BE MEDICALLY SIGNIFICANT.

B.6. Relevant tests/laboratory data - continued

LAB RESULT: 215
FASTING BLOOD SUGAR.

BLOOD GLUCOSE
FEB-2001 E
LAB RESULT: 200

BLOOD GLUCOSE
MAR-2001 E
LAB RESULT: 200-372
SINCE FEBRUARY, THE PATIENT HAS BEEN CHECKING HIS FASTING BLOOD SUGAR DAILY WITH A HOME KIT, AND IT HAS ALWAYS BEEN OVER 200 AND AS HIGH AS 372.

BLOOD GLUCOSE
2-MAY-2001
LAB RESULT: 0
MOST RECENT BLOOD SUGARS AROUND 200.

BLOOD GLUCOSE
BLOOD SUGARS OVER 200 WHEN DIABETES WAS DIAGNOSED (NO UNIT PROVIDED).

GLUCOSE_URINE
FEB-2001 E
URINE POSITIVE FOR SUGAR.

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

IBUPROFEN UNK
(IBUPROFEN)

G.3. Report Source (other:) - continued

PHARMACEUTICAL COMPANY

Individual Safety Report

3729166-3-00-01

.UNTARY reporting
professionals of adverse
nd product problems

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

FDA Use Only (MB)
Triage unit sequence # 14295

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

Patient information

Patient identifier: 193
Confidence:
2. Age at time of event: 76 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

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 (mo/day/yr)
☐ life-threatening
☒ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other:

Date of event (mo/day/yr): 10 30 00
4. Date of this report (mo/day/yr):

Describe event or problem

Weakness, dizziness, SOB.
mild tachycardia
GI Bleed.
Given 4u PRBC
Endoscopy showed ulcers
NSAIDS D'cd.

Relevant tests/laboratory data, including dates

HCT 22.2 down
from 41.3 2 weeks before

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

DM
Glaucoma
HTN
Arthritis

CTV144295

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Naproxen
#2
2. Dose, frequency & route used
#1 1-2 tabs BID
#2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 → 10/30/00
#2
4. Diagnosis for use (indication)
#1 arthritis
#2
5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
#1
#2
7. Exp. date (if known)
#1
#2
8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)
Misoprostol 200mcg qid
Prednisone 20mg tid.
ASA qd

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

RECEIVED
MAY 29 2001
MEDWATCH CTU

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)
VISN 17 - San Antonio/Kerrville
VA Hospitals - STVHCS

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
VA HOSPITAL (119)
7400 MERTON MINTER BLVD.
SAN ANTONIO, TX 78284
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharm D
4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

FDA

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

or FAX to:
1-800-FDA-0178

Individual Safety Report

3742214-X-00-01

MEDWATCH FORM ■ UPDATES

MEDWATCH

THE FDA MEDICAL PRODUCT REPORTING PROGRAM

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

Page ___ of ___

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

FDA Use Only (AMFS)

Image and sequence # 145654

A. Patient information

1. Patient identifier: 2-4-1770 (in confidence)
2. Age at time of event: 80 or Date of birth: [redacted]
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply): ☐ death ___ ☐ life-threatening ☒ hospitalization – initial or prolonged ☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other ___
3. Date of event: 5/3/00
4. Date of this report: 3/14/01
5. Describe event or problem: abdominal pain

(1) Admitted for ~~GI bleed~~, found to have perforated duodenal ulcer and underwent surgery. Postoperatively was treated with Zosyn initially + Pepcid, then clindamycin + ceftriaxone. Corticosteroids were continued. Developed renal failure + encephalopathy. Developed diffuse maculopapular rash + intermittent fever on 5/8. Antibiotics changed to Vancomycin + topical steroids added. Pepcid was stopped 5/10 as it was the only drug the pt. was still on from the time the rash developed. Rash fading 5/16. Discharged to specialty hospital on 5/23 for ongoing care.

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.)
COPD
Hypertension

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
   #1 Naprosyn
   #2 Prednisone
2. Dose, frequency & route used
   #1 Unknown
   #2 ~~[illegible]~~ Unknown
3. Therapy dates (if unknown, give duration)
   #1 Unknown
   #2 Unknown
4. Diagnosis for use (indication)
   #1 Unknown
   #2 COPD
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
    ~~Prednisone~~
    Cardura

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

RECEIVED
JUN 19 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 FDA) ☐ yes ☐ no ☐ returned to manufacturer on ___
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] St
2. Health professional? ☒ yes ☐ no
3. Occupation: Clinical Coordinator Pharmacy
4. Also reported to: ☐ manufacturer ☐ user facility ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

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

FDA Form 3500 (6/93)

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

CTU145654

21

Individual Safety Report

3743333-4-00-01

For VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 3/31/2
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 145850

Page ___ of ___

1. Patient identifier [redacted] In confidence
2. Age at time of event: 75 or Date of birth:
3. Sex: ☑ female ☐ male
4. Weight: ___ lbs or ___ kgs

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   ☐ death ___ (mo/day/yr)
   ☐ life-threatening
   ☐ hospitalization – initial or prolonged
   ☐ disability
   ☐ congenital anomaly
   ☐ required intervention to prevent permanent impairment/damage
   ☑ other: Erosive gastritis
3. Date of event (mo/day/yr): 6/5/01
4. Date of this report (mo/day/yr): 6/12/01
5. Describe event or problem

Occult blood in stool in April. Colonoscopy was negative. An endoscopy was performed 6/6/01 after patient complained of abdominal pain Scope indicated erosive gastritis

6. Relevant tests/laboratory data, including dates

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

History of depressive symptoms for 10 years, stable condition Status post hysterectomy, appendectomy, cholecystectomy

1. Name (give labeled strength & mfr/labeler, if known)
   #1 rofecoxib 25 mg po qd or
   #2 naproxen 200 mg po bid or placebo
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1 Alzheimer's disease
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☑ doesn't apply
6. Lot # (if known)
   #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)

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

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6. model #
   catalog #
   serial #
   lot #
   other #
5. Expiration date (mo/day/yr)
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

1. Name & address: [redacted] MD, [redacted] Dept of Neurology [redacted] Bldg
   phone # [redacted]
2. Health professional? ☑ yes ☐ no
3. Occupation: Physician
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 145850

Individual Safety Report

3748423-8-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by 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 [Intake Unit]

Triage unit sequence # 146209

A. Patient information

1. Patient identifier: XX (In confidence)
2. Age at time of event: 55YR or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [ ] death (mo/day/yr)
   - [ ] life-threatening
   - [X] hospitalization – initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other:
3. Date of event (mo/day/yr): 6-20-01
4. Date of this report (mo/day/yr): 6-27-01
5. Describe event or problem

GI BLEED: MELENA & ORTHOSTATIC HYPOTENSION. Patient w/ rheumatoid arthritis taking Naproxen came to Emer Room c/o syncopal episode. First time for these problems. Also c/o mild epigastric pain x a few weeks & melena. EXAM:P 125, BP 111/59, positive orthostatics, Hgb 4.4. Transfused w/ 2 units PRBC's; NG tube lavage. DG: GI bleed w/ orthostatic hypotension--probably d/t Naproxen use. Admitted for F/U.

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.)

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CTI/146209

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Naproxen
   #2 NAPROXEN
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (from/to (or most recent) or duration)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 [ ] yes [ ] no [ ] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 [ ] yes [ ] no [ ] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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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)

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JUN 28 2001

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
   MED CTR
   ST Rm [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation: PHARMACIST
4. Also reported to
   - [ ] manufacturer
   - [ ] user facility
   - [ ] distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [X]

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

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.

Serious
Clovis

MEDWatch

Approved by FDA on 10/20/93

Triage unit sequence # 147306

Clark

Individual Safety Report

3760008-6-00-01

A. Patient Information

1. Patient Indentifier [redacted]
2. DOB: [redacted] AGE: 81 yrs
3. Sex: MALE
4. Weight: 83.8 kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [ ] Product problem

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

3. Date of event: 06/25/01
4. Date of this report: 06/25/01

5. Describe event or problem
GI BLEED

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6. Relevant test/laboratory data, including dates

7. Other relevant History, including preexisting medical conditions
Pt had also been on prednisone, but had recently been tapered off.

C. Suspect Medication(s)

1. Name
#1 : NAPROXEN

2. Dose, frequency & route used
#1:

3. Therapy dates
#1 :

4. Diagnosis for use (indication)
#1:

5. Event abated after use stopped or dose reduced?
#1: [N/A]

6. Lot # (if known)
#1:

7. Exp. date
#1:

8. Event reappeared after reintroduction
#1: [ ]

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
RANITIDINE 150MG TAB
HYDROXYZINE 25MG CAP/TAB
TERAZOSIN 2MG CAP/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], PHARM.D.
%VAMC AMARILLO 6010 AMARILLO BLVD WEST
AMARILLO, TEXAS 79106 [redacted]

2. Health professional? [YES]
3. Occupation: CLINICAL PHARM
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.

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CTV147306

Individual Safety Report

3760008-6-00-02

147306

ATTACHMENT PAGE

PATIENT ID: [redacted]

SUSPECT MEDICATION: NAPROXEN

DATE OF EVENT: 6/25/01

Section C. Part 10. Concomitant Drugs Continued

HCTZ 25MG/TRIAMTERENE 37.5MG TAB

BISACODYL 5MG TAB

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147306

Individual Safety Report

3769065-4-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

FDA Use Only

Triage unit sequence # 148227

Page of

CDER

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: 78 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 7-14-00
4. Date of this report (mo/day/yr): 12-5-00
5. Describe event or problem

upper GI bleed
acute renal failure

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.)

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CTV148227

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 naproxyn
   #2
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (from/to or for how long)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☒ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other
5. Expiration date (mo/day/yr)
6. model #
   catalog #
   serial #
   lot #
   other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: pharmacist
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

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

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

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Individual Safety Report

3778293-3-00-01

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Triage unit sequence # 149199

Page

Patient identifier: 06-344

Age or time of event: 69

Date of birth:

Sex: ☐ male ☐ female

Weight: ___ lbs or ___ kg

B. Adverse event or product problem

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

Outcomes attributed to adverse event (check all that apply)

☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☒ other Resolved

Date of event: 04-00

Date of this report: 06-07-01

5. Describe event or problem

Erosions consistent with Nuprosyn use

Relevant tests/laboratory data

Other relevant history, including preexisting medical conditions

CTV149199

C. Suspect medication(s)

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

#1 Nuprosyn

Diagnosis for use (indication)

6. Lot # (if known) #1

7. Exp. date (if known) #1

9. NDC # (for product problems only)

Brand name

Type of device

Manufacturer name & address

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model #

catalog #

serial #

lot #

other #

Device available for evaluation?

Concomitant medical products

E. Reporter (see confidentiality section on back)

1. [redacted] Ph.D., FASCP, R.Ph.
Director of Pharmacy Services
[redacted] Avenue
P.O. Box [redacted]
Memorial Hospital [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to: ☒ manufacturer ☐ user facility ☐ distributor

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

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

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

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

Individual Safety Report

3778300-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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vents and product problems

FDA Use Only

Triage unit sequence # 149210

Page

CDER

055-452

Age at time of event: 50

Date of birth:

Sex: ☐ female ☐ male

Weight

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: Resolved

Date of event: 04-00

Date of this report: 06-07-01

5. Describe event or problem

Black tarry stools/several bloody stools on Coumadin

Relevant tests/laboratory data, including dates

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

CTV149210

C. Suspect medication(s)

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

#1 Naproxyn

#2

Diagnosis for use (indication)

#1

#2

6. Lot # (if known)

#1

7. Exp. date (if known)

#1

9. NDC # (for product problems only)

Brand name

Type of device

Manufacturer name & address

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model #

catalog #

serial #

lot #

other #

Device available for evaluation?

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Concomitant medical products and therapies

E. Reporter (see confidentiality section on back)

1. [redacted] Ph.D., FASCP, R.Ph.
Director of Pharmacy Services
975 South Fairmont [redacted]
P.O. Box [redacted]
[redacted] Memorial Hospital [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
☒ manufacturer
☐ user facility
☐ distributor

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

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

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

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

Individual Safety Report

3778413-0-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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Page ___ of ___

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

FDA Use Only

Triage unit sequence # 199122

A. Patient information

1. Patient identifier: 316-505 In confidence
2. Age at time of event: 74 or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   ☐ death (mo/day/yr)
   ☐ life-threatening
   ☐ hospitalization – initial or prolonged
   ☐ disability
   ☐ congenital anomaly
   ☐ required intervention to prevent permanent impairment/damage
   ☒ other: Resolved
3. Date of event (mo/day/yr): 08-00
4. Date of this report (mo/day/yr): 06-07-01
5. Describe event or problem

GI Bleed secondary to NSAID use

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.)

CTV 199122

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Naprosyn
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) (mo/day/yr 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
7. Exp. date (if known)
   #1
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

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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)

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AUG 16 2001

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

E. Reporter (see confidentiality section on back)

1. [redacted] Ph.D., FASCP, R.Ph.
   Director of Pharmacy Services
   [redacted] Avenue
   [redacted]
   Memorial Hospital [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to
   ☒ manufacturer
   ☐ user facility
   ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

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

FDA Form 3500 (6/93)

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

Individual Safety Report

3778591-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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alth professionals of adverse
nts and product problems

Page ___ of ___

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

FDA Use Only

Triage unit sequence # 149176

A. Patient information

1. Patient identifier: 087-886 (in confidence)
2. Age at time of event: 70 or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☒ other: Resolved
3. Date of event: 11-00
4. Date of this report: 06-17-01
5. Describe event or problem: GI Bleed
6. Relevant tests/laboratory data, including dates
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

DSS
AUG 16 2001

CTU 149176

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known): #1 Naprosyn
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
7. Exp. date (if known): #1
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
6. model # / catalog # / serial # / lot # / other #
7. If implanted, give date
8. If explanted, give date
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on
10. Concomitant medical products and therapy dates (exclude treatment of event)

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MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. [redacted] R.Ph. Director of Pharmacy Services [redacted] Avenue [redacted] Memorial Hospital [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to: ☒ manufacturer ☐ user facility ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

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

FDA Form 3500 (6/93)

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

Form Approved: OMB No. 0910-0291, Expires: 10/31/01
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3778714-6-00-01

VOLUNTARY reporting
by professionals of adverse
events and product problems

FDA Use Only
Triage unit sequence # 149070

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier: 253-203 In confidence
2. Age at time of event: 75 or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   ☐ death (mo/day/yr)
   ☐ life-threatening
   ☐ hospitalization – initial or prolonged
   ☐ disability
   ☐ congenital anomaly
   ☐ required intervention to prevent permanent impairment/damage
   ☒ other: Resolved
3. Date of event (mo/day/yr): 10-00
4. Date of this report (mo/day/yr): 06-17-01
5. Describe event or problem
   GI Bleed NSAID related
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.)
   CTV149040

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Naprosyn
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
7. Exp. date (if known)
   #1
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 ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

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AUG 15 2001
MEDWATCH CTU

DSS
AUG 16 2001

E. Reporter (see confidentiality section on back)

1. [redacted] Ph.D., FASCP, R.Ph.
   Director of Pharmacy Services
   [redacted] Avenue
   [redacted]
   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. ☐

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.

10-24- 1 ;12:20PM ; [redacted] DRUG INFO →

SENT BY:

Individual Safety Report

3814529-8-00-01

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

FDA use only (tracking)

Image unit assigned # 154409

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page 1 of 1

A. Patient information

1. Patient identifier: XX (In confidence)
2. Age at time of event: 61yR or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 9-23-01
4. Date of this report (mo/day/yr): 10-24-01
5. Describe event or problem

GASTROINTESTINAL BLEED: HEMATEMESIS. Patient w/ arthritis, asthma, HTN, & h/o GI bleed 8 months ago taking Naproxen (500mg BID per PADI) admitted to hospital c/o hematemesis x 2 days. No abdominal pain, no CP, no SOB. Denies melena, hematochezia, diarrhea. P 55, BP 102/66, R 18. Treated in Emer Room w/ 2 units PRBC's & admitted for F/U.

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.)

OCT 24 2001

CTV154409

C. Suspect medication(s)

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

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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OCT 25 2001

MEDWATCH CTU

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)

DSS

OCT 26 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted] MED CTR ST Rm [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: PHARMACIST
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

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

FDA Form 3500 (6/93)

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

Individual Safety Report

3817085-3-00-01

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

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page 1 of 1

FDA Use Only (Internal): Tracking and Reference # 154662

A. Patient information

1. Patient identifier: XX (In confidence)
2. Age at time of event: 53y or Date of birth:
3. Sex: [ ] female [X] male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply): [ ] death ___ (mo/day/yr) [ ] life-threatening [X] hospitalization – initial or prolonged [ ] disability [ ] congenital anomaly [ ] required intervention to prevent permanent impairment/damage [ ] other:
3. Date of event (mo/day/yr): 6-19-01
4. Date of this report (mo/day/yr): 9-27-01
5. Describe event or problem

GASTROINTESTINAL BLEEDING: MELENA. Patient w/ Gout, HTN, CHF, A-Fib, & CRI came to hospital after developed sharp epigastric discomfort & black stool after taking Naproxen for a few days for gout flare. MI ruled out; EGD showed 3 antral ulcers.; H/H stable. Final DG: UGI bleed d/t antral ulcer.

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.)

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SEP 27 2001
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CTV154662

C. Suspect medication(s)

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

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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MEDWATCH CTU

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)

OCT 30 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] MED CTR Rm [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation: PHARMACIST
4. Also reported to: [ ] manufacturer [ ] user facility [ ] distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [X]

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

3818487-1-00-01

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

Page ___ of [redacted]

Form approved: OMB No. 0910-0291 Expires: 12/31/A
See OMB statement on revers

FDA Use Only H Fed

Triage unit sequence # 154902
Faxed to CDER/OPDRA

A. Patient information

1. Patient Identifier: [redacted] In confidence
2. Age at time of event: or 89 / Date of birth: [redacted]
3. Sex: [X] female [ ] male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [X] death 07/09/01 (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): 7/7/01
4. Date of this report (mo/day/yr): 10/31/01
5. Describe event or problem

Patient was on Naprosyn – dose unknown and frequency unknown – at home. Site developed a perforated duodenal ulcer + GI bleed. and peritonitis This led to sepsis and renal failure. and death.

6. Relevant tests/laboratory data, including dates

Endoscopy/Gastroscopy 7/7/01

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

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CTV154902

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Naprosyn (Roche)
   #2
2. Dose, frequency & route used
   #1 unknown
   #2
3. Therapy dates (if unknown, give duration) (mo/day/yr 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 [X] doesn't apply
   #2 [ ] yes [ ] no [X] doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 [ ] yes [ ] no [X] doesn't apply
   #2 [ ] yes [ ] no [X] 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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NOV 01 2001
MEDWATCH CTU

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)

DSS
NOV 01 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] Hospital
   [redacted] Road
   [redacted] Attn: Pharmacy Dept.
2. Health professional? [X] yes [ ] no
3. Occupation: Pharmacist
4. Also reported to
   - [ ] manufacturer
   - [ ] user facility
   - [ ] distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [X]

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

3821774-4-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

'OLUNTARY reporting by 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 # 155090

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: or Date of birth: [redacted]
3. Sex: ☑ female ☐ male
4. Weight: lbs or 77 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): 10/07/2001
4. Date of this report (mm/dd/yyyy): 11/02/2001
5. Describe event or problem

GI bleed; Bloody stools

6. Relevant tests/laboratory data, including dates

EGD showed large jejunal ulcer HCT on admit = 20 Blood in stool

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

Gastric bypass 1998 Pilonidal cyst

MEDWATCH NOV 07 2001

CTV155090

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
   - #1 Naproxen
   - #2
2. Dose/Frequency/Route used
   - #1 2-3/day x 1 / Oral
   - #2
3. Therapy dates (if unknown, give duration) From To (or best estimate)
   - #1 –
   - #2 –
4. Diagnosis for use (separate indications with commas)
   - #1 pilonidal cyst
   - #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

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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]

[redacted] Hospital; Inpatient Pharmacy; [redacted] DSS
[redacted] Ave.
[redacted] [redacted] [redacted]
United States

NOV 08 200

2. Health professional? ☑ yes ☐ no
3. Occupation: Other Health Professional
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

Fax to: 1-800-FDA-0178

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

Individual Safety Report

3836537-3-00-01

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Approved by FDA on 10/20/93

Triage unit sequence # 156932

A. Patient Information

1. Patient Identifier: 92163
2. DOB: [redacted] AGE: 68 yrs
3. Sex: MALE
4. Weight: 91.6 kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [ ] Product problem
2. Outcomes attributed to adverse event
   - [ ] death
   - [X] life-threatening
   - [X] Hospitalization initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [X] required intervention to prevent impairment/damage
   - [ ] other
3. Date of event: 10/25/01
4. Date of this report: 11/30/01
5. Describe event or problem: GASTROINTESTINAL HEMORRHAGE
6. Relevant test/laboratory data, including dates
7. Other relevant History, including preexisting medical conditions

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C. Suspect Medication(s)

1. Name: #1 : NAPROXEN
2. Dose, frequency & route used: #1:
3. Therapy dates: #1:
4. Diagnosis for use (indication): #1:
5. Event abated after use stopped or dose reduced? #1: [N/A]
6. Lot # (if known): #1:
7. Exp. date: #1:
8. Event reappeared after reintroduction: #1: [ ]
9. (Not applicable to adverse drug event reports)
10. Concomitant medical products/therapy dates (exclude treatment)

D. Suspect Medical Devices

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

E. Reporter

1. Name, address & phone #: [redacted]
   Pharmacy Service (119) VA Medical Center
   St. Cloud, MINNESOTA 56303 [redacted]
2. Health professional? [YES]
3. Occupation: PHARMACY STUDE
4. Reported to Mfr.: [NO]
5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

DSS DEC 10 2001

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

or FAX to: 1-800-FDA-0178

MEDWATCH

FDA Form 3500

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

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156932

DEC.19.2001 1:21PM PHARMACY

Individual Safety Report

3843289-X-00-01

Approved by FDA on 10/20/93

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 157512

Faxed to B. Bonzel (OPDRA)

A. Patient Information

1. Patient Indentifier [redacted]
2. DOB: [redacted] AGE: 60 yrs
3. Sex: MALE
4. Weight: 86.2 kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [ ] Product problem

2. Outcomes attributed to adverse event
   - [X] death: 12/03/01
   - [X] life-threatening
   - [X] Hospitalization initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [X] required intervention to prevent impairment/damage
   - [ ] other

3. Date of event: 11/29/01
4. Date of this report: 12/17/01

5. Describe event or problem
DIARRHEA , GI BLEED

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DEC 20 2001
MEDWATCH CTU

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

7. Other relevant History, including preexisting medical conditions
was in usual state of health until thanksgiving, developed cold chills, then had progressive weakness, seen in ER for knee pain, was given naprosyn, thne saw Surgery and cpc team 2 d agcp had weakness and rectal bleeding felt due to
PLEASE SEE ATTACHED

C. Suspect Medication(s)

1. Name
#1 : NAPROSYN

2. Dose, frequency & route used
#1:

3. Therapy dates
#1 :

4. Diagnosis for use (indication)
#1:

5. Event abated after use stopped or dose reduced?
#1: [N/A]

6. Lot # (if known)
#1:

7. Exp. date
#1:

8. Event reappeared after reintroduction
#1: [ ]

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
ASPIRIN 81MG EC TAB
DIGOXIN (LANOXIN) 0.25MG TAB
FUROSEMIDE 40MG 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? [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. [ ]

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 157512

Individual Safety Report

3843289-X-00-02

P 2 of 4

157512

ATTACHMENT PA...

PATIENT ID: [redacted]

SUSPECT MEDICATION: NABROSYN

DATE OF EVENT: 11/29/01@10:51

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

TEST: LDH RESULTS: 497. U/L H:618/L:313 COLLECTION DATE: 11/29/01@09:09
TEST: PROTEIN,TOTAL RESULTS: L 4.4 GM/DL H:8.2/L:6.3 COLLECTION DATE: 11/29/01@09:09
TEST: ALBUMIN RESULTS: L 1.7 GM/DL H:5/L:3.5 COLLECTION DATE: 11/29/01@09:09
TEST: TOT. BILIRUBIN RESULTS: H 2.3 MG/DL H:1.3/L:.2 COLLECTION DATE: 11/29/01@09:09
TEST: AST (SGOT) RESULTS: 48. IU/L H:59/L:17 COLLECTION DATE: 11/29/01@09:09
TEST: ALT (SGPT) RESULTS: 24. IU/L H:72/L:21 COLLECTION DATE: 11/29/01@09:09
TEST: ALKPHOS RESULTS: H 151. IU/L H:126/L:38 COLLECTION DATE: 11/29/01@09:09
TEST: GGT RESULTS: H 95. IU/L H:73/L:15 COLLECTION DATE: 11/29/01@09:09
TEST: TROPONIN I RESULTS: 0.4 ng/mL H:2/L:0 COLLECTION DATE: 11/29/01@08:05
TEST: WBC RESULTS: H 16.9 K/uL H:9.7/L:4.2 COLLECTION DATE: 11/29/01@08:05
TEST: RBC RESULTS: L 3.21 M/uL H:5.56/L:4.24 COLLECTION DATE: 11/29/01@08:05
TEST: HGB RESULTS: L 9.6 G/DL H:16.9/L:13.2 COLLECTION DATE: 11/29/01@08:05
TEST: HCT RESULTS: L 28.7 %VOLUME H:50.5/L:39.5 COLLECTION DATE: 11/29/01@08:05
TEST: MCV RESULTS: 89.4 fL H:100.5/L:83.5 COLLECTION DATE: 11/29/01@08:05
TEST: MCH RESULTS: 30.0 pg H:33.8/L:27.3 COLLECTION DATE: 11/29/01@08:05
TEST: MCHC RESULTS: 33.5 g/dl H:36/L:32 COLLECTION DATE: 11/29/01@08:05
TEST: PLT RESULTS: L 88 K/uL H:400/L:130 COLLECTION DATE: 11/29/01@08:05
TEST: RDW RESULTS: H 16.1 % H:15.5/L:11.6 COLLECTION DATE: 11/29/01@08:05
TEST: MPV RESULTS: 7.8 fL H:10.9/L:6.7 COLLECTION DATE: 11/29/01@08:05
TEST: PT RESULTS: H* 22.0 SEC H:13.1/L:10.2 COLLECTION DATE: 11/29/01@08:05
TEST: APTT RESULTS: pending SEC H:35.7/L:23.6 COLLECTION DATE: 11/29/01@08:05
TEST: LDH RESULTS: 496. U/L H:618/L:313 COLLECTION DATE: 11/29/01@08:05
TEST: GLUCOSE RESULTS: 108. MG/DL H:110/L:75 COLLECTION DATE: 11/29/01@08:05
TEST: UREA N RESULTS: pending MG/DL H:20/L:9 COLLECTION DATE: 11/29/01@08:05
TEST: CREATININE RESULTS: H 4.0 MG/DL H:1.5/L:.8 COLLECTION DATE: 11/29/01@08:05
TEST: URIC ACID RESULTS: H 9.7 MG/DL H:8.5/L:3.5 COLLECTION DATE: 11/29/01@08:05
TEST: SODIUM RESULTS: 137. MMOL/L H:145/L:137 COLLECTION DATE: 11/29/01@08:05
TEST: POTASSIUM RESULTS: 4.3 MMOL/L H:5/L:3.6 COLLECTION DATE: 11/29/01@08:05
TEST: CHLORIDE RESULTS: 106.4 MMOL/L H:107/L:98 COLLECTION DATE: 11/29/01@08:05
TEST: CO2 RESULTS: 22.0 MMOL/L H:30/L:22 COLLECTION DATE: 11/29/01@08:05
TEST: MAGNESIUM RESULTS: H 2.9 MG/DL H:2.3/L:1.6 COLLECTION DATE: 11/29/01@08:05
TEST: CALCIUM RESULTS: 9.3 MG/DL H:10.2/L:8.4 COLLECTION DATE: 11/29/01@08:05
TEST: PHOSPHORUS RESULTS: 2.7 MG/DL H:4.5/L:2.5 COLLECTION DATE: 11/29/01@08:05
TEST: PROTEIN,TOTAL RESULTS: L 4.5 GM/DL H:8.2/L:6.3 COLLECTION DATE: 11/29/01@08:05
TEST: ALBUMIN RESULTS: L 1.7 GM/DL H:5/L:3.5 COLLECTION DATE: 11/29/01@08:05
TEST: TOT. BILIRUBIN RESULTS: H 2.3 MG/DL H:1.3/L:.2 COLLECTION DATE: 11/29/01@08:05
TEST: AST (SGOT) RESULTS: 49. IU/L H:59/L:17 COLLECTION DATE: 11/29/01@08:05
TEST: CPK RESULTS: 124. IU/L H:170/L:55 COLLECTION DATE: 11/29/01@08:05
TEST: ALKPHOS RESULTS: H 148. IU/L H:126/L:38 COLLECTION DATE: 11/29/01@08:05
TEST: APPEARANCE RESULTS: CLOUDY COLLECTION DATE: 11/29/01
TEST: SPECIFIC GRAVITY RESULTS: 1.017 H:1.030/L:1.005 COLLECTION DATE: 11/29/01
TEST: URINE PROTEIN RESULTS: 30 MG/DL COLLECTION DATE: 11/29/01
TEST: URINE GLUCOSE RESULTS: NEG MG/DL COLLECTION DATE: 11/29/01
TEST: URINE KETONES RESULTS: NEG MG/DL COLLECTION DATE: 11/29/01
TEST: URINE BILIRUBIN RESULTS: NEG COLLECTION DATE: 11/29/01
TEST: URINE BLOOD RESULTS: NEG COLLECTION DATE: 11/29/01
TEST: UROBILINOGEN RESULTS: 1.0 E.U./DL H:1/L:.2 COLLECTION DATE: 11/29/01
TEST: URINE PH RESULTS: 5.00 H:9/L:5 COLLECTION DATE: 11/29/01
TEST: NITRITE, URINE RESULTS: NEG COLLECTION DATE: 11/29/01
TEST: LEU ASE RESULTS: NEG COLLECTION DATE: 11/29/01
TEST: URINE COLOR RESULTS: AMBER COLLECTION DATE: 11/29/01
TEST: APTT COAG PT RESULTS: 16.8 SEC H:23/L:17 COLLECTION DATE: 11/27/01@12:33
TEST: INR RESULTS: 2.1 RATIO H:3.5/L:2 COLLECTION DATE: 11/27/01@12:33
TEST: APPEARANCE RESULTS: CLOUDY COLLECTION DATE: 11/27/01@10:11
TEST: SPECIFIC GRAVITY RESULTS: 1.023 H:1.030/L:1.005 COLLECTION DATE: 11/27/01@10:11
TEST: URINE PROTEIN RESULTS: 100 MG/DL COLLECTION DATE: 11/27/01@10:11
TEST: URINE GLUCOSE RESULTS: NEG MG/DL COLLECTION DATE: 11/27/01@10:11
TEST: URINE KETONES RESULTS: TRACE MG/DL COLLECTION DATE: 11/27/01@10:11
TEST: URINE BILIRUBIN RESULTS: SMALL COLLECTION DATE: 11/27/01@10:11
TEST: URINE BLOOD RESULTS: SMALL COLLECTION DATE: 11/27/01@10:11

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p. 3 of 7

TEST: UROBILINOGEN RESULTS: 1.0 E.U./DL H:1/L:.2 COLLECTION DATE: 11/27/01@10:11
TEST: URINE PH RESULTS: 5.00 H:9/L:5 COLLECTION DATE: 11/27/01@10:11
TEST: NITRITE, URINE RESULTS: NEG COLLECTION DATE: 11/27/01@10:11
TEST: LEU ASE RESULTS: TRACE COLLECTION DATE: 11/27/01@10:11
TEST: URINE COLOR RESULTS: ORANGE COLLECTION DATE: 11/27/01@10:11
TEST: URINE WBC/HPF RESULTS: 0-3 CELLS/HPF H:5/L:0 COLLECTION DATE: 11/27/01@10:11
TEST: URINE RBC/HPF RESULTS: 0-3 CELLS/HPF COLLECTION DATE: 11/27/01@10:11
TEST: URINE BACTERIA RESULTS: 3+ COLLECTION DATE: 11/27/01@10:11
TEST: GRANULAR CASTS RESULTS: 16-18 CASTS/LPF COLLECTION DATE: 11/27/01@10:11
TEST: RPR RESULTS: Nonreactive COLLECTION DATE: 11/27/01@09:35
TEST: PSA RESULTS: 2.75 ng/ml H:4/L:0 COLLECTION DATE: 11/27/01@09:35
TEST: LDH RESULTS: H 627. U/L H:618/L:313 COLLECTION DATE: 11/27/01@09:35
TEST: GLUCOSE RESULTS: 81. MG/DL H:110/L:75 COLLECTION DATE: 11/27/01@09:35
TEST: UREA N RESULTS: H 66. MG/DL H:20/L:9 COLLECTION DATE: 11/27/01@09:35
TEST: CREATININE RESULTS: H 3.0 MG/DL H:1.5/L:.8 COLLECTION DATE: 11/27/01@09:35
TEST: SODIUM RESULTS: L 136. MMOL/L H:145/L:137 COLLECTION DATE: 11/27/01@09:35
TEST: POTASSIUM RESULTS: 3.9 MMOL/L H:5/L:3.5 COLLECTION DATE: 11/27/01@09:35
TEST: CHLORIDE RESULTS: 102.9 MMOL/L H:107/L:98 COLLECTION DATE: 11/27/01@09:35
TEST: CO2 RESULTS: 23.0 MMOL/L H:30/L:22 COLLECTION DATE: 11/27/01@09:35
TEST: ALBUMIN RESULTS: L 2.4 GM/DL H:5/L:3.5 COLLECTION DATE: 11/27/01@09:35
TEST: TOT. BILIRUBIN RESULTS: H 3.1 MG/DL H:1.3/L:.2 COLLECTION DATE: 11/27/01@09:35
TEST: DIR. BILIRUBIN RESULTS: H 2.5 MG/DL H:.4/L:0 COLLECTION DATE: 11/27/01@09:35
TEST: AST (SGOT) RESULTS: 27. IU/L H:59/L:17 COLLECTION DATE: 11/27/01@09:35
TEST: ALT (SGPT) RESULTS: <24 IU/L H:72/L:21 COLLECTION DATE: 11/27/01@09:35
TEST: ALKPHOS RESULTS: 122. IU/L H:126/L:38 COLLECTION DATE: 11/27/01@09:35
TEST: GGT RESULTS: H 95. IU/L H:73/L:15 COLLECTION DATE: 11/27/01@09:35
TEST: CHOLESTEROL RESULTS: 116. MG/DL H:200/L: COLLECTION DATE: 11/27/01@09:35
TEST: TRIGLYCERIDE RESULTS: H 345. MG/DL H:250/L:0 COLLECTION DATE: 11/27/01@09:35
TEST: HDL RESULTS: <6.3 MG/DL COLLECTION DATE: 11/27/01@09:35
TEST: LDL CHOLESTEROL RESULTS: comment MG/DL H:130/L: COLLECTION DATE: 11/27/01@09:35
TEST: WBC RESULTS: 6.7 K/uL H:9.7/L:4.3 COLLECTION DATE: 11/26/01@17:53
TEST: RBC RESULTS: L 4.07 M/uL H:5.56/L:4.24 COLLECTION DATE: 11/26/01@17:53
TEST: HGB RESULTS: L 12.0 G/DL H:16.9/L:13.2 COLLECTION DATE: 11/26/01@17:53
TEST: HCT RESULTS: L 36.9 %VOLUME H:50.5/L:39.5 COLLECTION DATE: 11/26/01@17:53
TEST: MCV RESULTS: 90.6 fL H:100.5/L:83.5 COLLECTION DATE: 11/26/01@17:53
TEST: MCH RESULTS: 29.4 pg H:33.8/L:27.3 COLLECTION DATE: 11/26/01@17:53
TEST: MCHC RESULTS: 32.4 g/dl H:36/L:32 COLLECTION DATE: 11/26/01@17:53
TEST: PLT RESULTS: L 80 K/uL H:400/L:130 COLLECTION DATE: 11/26/01@17:53
TEST: RDW RESULTS: H 15.6 % H:15.5/L:11.6 COLLECTION DATE: 11/26/01@17:53
TEST: MPV RESULTS: 7.2 fL H:10.9/L:6.7 COLLECTION DATE: 11/26/01@17:53
TEST: SEGS RESULTS: H 80 % H:70/L:40 COLLECTION DATE: 11/26/01@17:53
TEST: BANDS RESULTS: H 10 % H:8/L:0 COLLECTION DATE: 11/26/01@17:53
TEST: LYMPHS RESULTS: L 6 % H:37/L:17 COLLECTION DATE: 11/26/01@17:53
TEST: MONOS RESULTS: 5 % H:8/L:0 COLLECTION DATE: 11/26/01@17:53
TEST: PLT (ESTM) RESULTS: REDUCED COLLECTION DATE: 11/26/01@17:53
TEST: NORMREC RESULTS: YES COLLECTION DATE: 11/26/01@17:53

Individual Safety Report

3843289-X-00-03

Section B. Part 7. Other Relevant History Continued
radiation proctitis, presently is bedfast , lethargic but coherant, too weak to sign consent but comprehends. had large black BM this am that was blood tinged, had 2nd large black blood tinged stool in ER heme+. Is on coumadin for afib, also on aspirin. platelet 2 d ago 80K. hgb was 12. also I note elevation of direct bili with nl enzymes c/w hemolysis. old lab studies from private physician Dr Caplett requested. Pt consents to blood transfusion. He is DNR and has advanced directives, son is NPOA.has had poor po intake, has become incontinent of urine and stool. was caring for himself and ambulatory 1 week ago. past hx prostate cancer, AAA repair. no hx ulcers. exam extremly weak pale heent anicteric, no jvd. mouth very dry lungs clear corr rate 70's regular abd soft . healed midline scar not tender. stool heme + black blood tinged. ext trace edema. note pt also given lasix and NTG by rescue squad en route.

protime 22 hgb 9.6 plt 89k, wbc 16.9

cxr reported as pneumonia

assess: upper gi bleed , anticoagulated and on antiplatelet meds, thrombocytopenia etiology? renal insufficiency ? acuity pneumonia by cxr

plan ICU care transfuse FFP stat transfuse 2 u prbc discussed with [redacted]

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P 4-6 4

157512

/es/ ROBERT R. MORAN, MD Signed: 11/29/2001 10:08

Section C. Part 10. Concomitant Drugs Continued

LISINOPRIL 20MG TAB

POTASSIUM CHLORIDE 10MEQ SA TAB

TERAZOSIN HCL 10MG CAP

Individual Safety Report

3843289-X-00-04

157512

WYETH AYERST

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ST. L..

Individual Safety Report
3236922-7-00-01

MEDWATCH

DUCTS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report # 8-98184-001M

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 21 YR or Date of birth: Unknown
3. Sex: [X] female [ ] male
4. Weight: 110 lbs or kgs

B. Adverse event or product problem

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

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

- [ ] death (mo/day/yr)
- [ ] life-threatening
- [X] hospitalization – initial or prolonged
- [X] recovered
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other:

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

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

5. Describe event or problem

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

6. Relevant tests/laboratory data, including dates

None provided

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

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

DATE SENT TO FDA: 09 / 14 / 98

C. Suspect medication(s)

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

#1 DURACT

#2 MOTRIN (IBUPROFEN)

2. Dose, frequency & route used

#1 1 capsule daily ORAL

#2 Unknown

3. Therapy dates (if unknown, give duration)

#1 11 / 00 / 97 to Unknown

#2 Unknown

4. Diagnosis for use (indication)

#1 BRUISED RIB

#2 Unknown

5. Event abated after use stopped or dose reduced

#1 [ ] yes [X] no [ ] doesn't apply

#2 [ ] yes [X] no [ ] doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 [ ] yes [ ] no [X] doesn't apply

#2 [ ] yes [ ] no [X] doesn't apply

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

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

Unknown

G. All manufacturers

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

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

KAREL F. BERMADY, PH.D.

2. Phone number: (610) 902-3760

3. Report source (check all that apply)

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

4. Date received by manufacturer (mo/day/yr): 06 / 30 / 98

5. (A)NDA # 20-535
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)

- [ ] 5-day
- [ ] 10-day
- [X] initial
- [ ] 15-day
- [X] periodic
- [ ] follow-up #

8. Adverse event term(s)

GASTROINTESTINAL HEMORRHAGE

9. Mfr. report number

8-98184-001M

E. Initial reporter

1. Name, address & phone #

[redacted]

SEP 15 1998

25

2. Health professional? [ ] yes [X] no

3. Occupation: N/A

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk.

FDA Form 3500A (facsimile)

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

WYETH AYERST

WYETH-A
170 RADN
DAVII

Individual Safety Report
3236822-7-00-02

MEDWATCH

TS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report # 8-38184-0013

UF/Dist report #

FDA Use Only

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#3 NAPROSYN (NAPROXEN)
#4

2. Dose, frequency & route used
#3 Unknown
#4

3. Therapy dates (if unknown, give duration)
#3 Unknown
#4

4. Diagnosis for use (indication)
#3 Unknown
#4

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

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

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

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)

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

SEP 15 1999

FDA Form 3500A (facsimile)

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

Individual Safety Report

3241328-0-00-01

5 LOPC

Approved by FDA on 10/20/93

CDER | Triage unit sequence # 101285

A. Patient Information

1. Patient Indentifier: [redacted]928
2. DOB: 7/1/27 AGE: 71 yrs
3. Sex: MALE
4. Weight: 0.0

B. Adverse Event or Product Problem

1. [X] Adverse Event [ ] Product problem

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

3. Date of event: 03/12/99

4. Date of this report: 03/[illegible]

5. Describe event or problem
GI BLEED

DSS

APR 1 9 1999

ADVERSE EVENT REPORTING SYSTEM

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

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

C. Suspect Medication(s)

1. Name
   #1 : NAPROXEN

2. Dose, frequency & route used
   #1:

3. Therapy dates
   #1 :

4. Diagnosis for use (indication)
   #1:

5. Event abated after use stopped or dose reduced?
   #1: [N/A]

6. Lot # (if known)
   #1:

7. Exp. date
   #1:

8. Event reappeared after reintroduction
   #1: [ ]

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
    DIGOXIN 0.25MG TAB
    SIMVASTATIN 5MG TAB
    TERAZOSIN 2MG 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] PHARM.D, BCPS
   %VAMC AMARILLO 6010 AMARILLO BLVD WEST
   AMARILLO, TEXAS 79106 [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-017

FDA Form 3500

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

CTU 101285

Individual Safety Report

3241328-0-00-02

101285

SPECT MEDICATION: NAPROXEN

DATE OF EVENT: 3/12/99

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

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

Section C. Part 10. Concomitant Drugs Continued

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

DSS

APR 19 1999

ADVERSE EVENT REPORTING SYSTEM

CTU 101285