9

9

ATTACHMENT I

Safety Reports
OTC NSAID: Ketoprofen

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

GI bleeding related to Keoprofen
Case Reports Submitted on GI Bleeding reported in association with OTC NSAIDs Ketoprofen cases (3) reported for January 1998 - December 2001

RECEIVED AT DRUG SAFETY SURVEILLANCE

16-JUN-1998-0592

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

med.

CDER

Individual Safety Report

3894136-8-00

95120

A. Patient Information

1. Patient Indentifier [redacted]
2. DOB: [redacted] AGE: 76 yrs
3. Sex: MALE
4. Weight: 92.0 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: 04/05/98
4. Date of this report: 06/02/98

5. Describe event or problem
UGI BLEED

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

7. Other relavant History, including preexisting medical conditions
PT WAS ADMITTED WITH 10-15 EPISODES OF COFFEE GROUND EMESIS & MILD EPIGASTRIC PAIN. PT APPARENTLY TAKING KETOPROFEN (UNKNOWN DOSAGE / FREQUENCY) X 3 YRS FROM EITHER PRIVATE MD / OTC PER PT'S DISCHARGE SUMMARY - EGD PLEASE SEE ATTACHED

C. Suspect Medication(s)

1. Name
   #1 : KETOPROFEN
2. Dose, frequency & route used
   #1: UNKNOWN, UNKNOWN, ORAL
3. Therapy dates
   #1 : 04/01/95-04/05/98
4. Diagnosis for use (indication)
   #1: UNKNOWN
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 treat

REC'D.

JUN 16 1998

MEDWATCH CTU

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
SVAMC 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 Manufac 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 even

SK120

RECEIVED AT DRUG SAFETY SURVEILLANCE

16-JUN-1998-0593

SUSPECT MEDICATIO

Individual Safety Report

3094136-8-98

86120

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

TEST: oHGB RESULTS: 13.8 gm/dL H:18/L:12 COLLECTION DATE: 4/5/98@19:4

TEST: HCT RESULTS: 42.5 % H:52/L:37 COLLECTION DATE: 4/5/98@19:43

Section B. Part 7. Other Relevant History Continued

DURING ADMISSION REVEALED GASTRIC ULCERS & BARRETT'S ESOPHAGUS. PT DISCHARGED ON LANSOPRAZOLE - ASPIRIN / TICLOPIDINE WITH PLANS TO START COUMADIN IN 1 WEEK FOR NEWLY DX'D CVA / LEFT VENTRICULAR THROMBUS PER ECHOCARDIOGRAM

REC'D.
JUN 16 1998
MEDWATCH CTU

85120

RECEIVED AT DRUG SAFETY SURVEILLANCE

29-APR-1998-0847

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use ... ributors ... MAND.

Page

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

Individual Safety Report

3160487-1-00-01

1086)

FDA Use Only

A. Patient information

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

B. Adverse event or product problem

1. [XX] 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
   - [XX] hospitalization – initial or prolonged
   - [XX] disability
   - [ ] congenital anomaly
   - [ ] recurred intervention to prevent permanent impairment/damage
   - [ ] other
3. Date of event (mo/day/yr): 11/21/96
4. Date of this report (mo/day/yr): 04/17/98
5. Describe event or problem

From the Summons and Complaint Notice:
A plaintiff reports having used Orudis KT tablets for control of minor arthritic pain in the amount prescribed by the packaging label (exact dose and duration are unknown). On November 21, 1996, the plaintiff, who has a medical history of diverticulitis, was admitted to the hospital and was treated for rectal bleeding and abdominal cramping. She was discharged (date unknown) and later rehospitalized for a similar incident. No further information is known at this time.

6. Relevant tests/laboratory data, including dates

No information provided.

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

diverticulitis

Allergy history unknown.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Orudis (R) KT Tablets
   - #2 -NA
2. Dose, frequency & route used
   - #1 unknwon
   - #2 -NA
3. Therapy dates (if unknown, give duration) (from-to or best estimate)
   - #1 Duration unk.
   - #2
4. Diagnosis for use (indication)
   - #1 minor arthritic pain
   - #2 -NA
5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [ ] no [XX] doesn't apply
   - #2 [ ] yes [ ] no [XX] doesn't apply
6. Lot # (if known)
   - #1 Unknown
   - #2 -NA
7. Exp. date (if known)
   - #1 -NA
   - #2 -NA
8. Event reappeared after reintroduction
   - #1 [ ] yes [ ] no [XX] doesn't apply
   - #2 [ ] yes [ ] no [XX] doesn't apply
9. NDC # – for product problems only (if known): 0573 - 0130 -
10. Concomitant medical products and therapy dates (exclude treatment of event)

None reported.

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - [ ] health professional
   - [ ] lay user patient
   - [ ] other
5. Expiration date (mo/day/yr)
6. model # / 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. Initial reporter

1. [redacted] Esq.
   [redacted] Blvd. suite [redacted]
   [redacted] United States
2. Health professional? [ ] yes [XX] no
3. Occupation: -NA
4. Initial reporter also sent report to FDA: [ ] yes [ ] no [XX] unk

FDA

FDA Form 3500A (6/93)

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

4/22/98

4/20/98

00-0019

WYETH
Individual Safety Report
3526918-X-00-01

WYETH-
BOX 829
PHILADE

MEDWATCH

'S REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ8164505JUL2000

UF/Dist report #

FDA Use Only

2

A. Patient Information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: or UNK; Date of Birth:
3. Sex: [X] female [ ] male
4. Weight: UNK 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): 06/22/1999
4. Date of this report (mo/day/yr): 07/07/2000

5. Describe event or problem

Information has been received 03-JUL-2000 from an Attorney concerning a female patient. The patient's concurrent illnesses include broken finger (Limb injury NOS). Therapy with ORUDIS KT CAPLET for Pain NOS began in JUL-1999 and ceased in JUL-1999. The product was taken as instructed on the product label, for several days. Concomitant therapy included UNSPECIFIED VITAMINS and UNSPECIFIED ESTROGEN REPLACEMENT THERAPY. On 20-Jul-1999, patient reported to the emergency room with severe flank pain. Tests revealed bloody urine and elevated white cells in blood Patient was prescribed Vicodin and released with a tentative diagnosis of possible kidney stone. On 22-JUL-2000, patient was taken to emergency room with symptoms of flank pain and rectal bleeding. Patient was diagnosed with gastritis (Gastritis NOS) or gastric ulcer (Gastric ulcer). On 24-JUL-1999, the patient underwent resection of colon (Colon anterior resection) . The pathology report stated, 'the resected colonic segment shows necrotizing

(cont'd)

6. Relevant tests/laboratory data, including dates

See following page.

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

CONCURRENT CONDITIONS:
Limb injury NOS

CENTER FOR DRUG
REC'D
JUL 10 2000
CDR
EVALUATION AND RESEARCH

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ORUDIS KT CAPLET
#2

2. Dose, frequency & route used
#1 as instructed on product label, Oral
#2

3. Therapy dates (if unknown, give duration)
#1 07/00/1999 to 07/00/1999
#2

4. Diagnosis for use (indication)
#1 Pain NOS
#2

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

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

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

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

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

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

G. All manufacturers

1. Contact office - name/address
WHITEHALL-ROBINS
c/o WYETH LABS (RA)
240 N Radnor-Chester
St. Davids, PA 19087

Jill Robinson

JUL 10 2000

2. Phone number: 6109024647

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): 07/03/2000

5. (A)NDA 20-429
IND #
PLA #
pre-1938 [ ] yes
OTC product [X] yes

6. If IND, protocol #

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

8. Adverse event term(s)
Colon anterior resection
Gastritis NOS
Gastric ulcer

DSS

JUL 11 2000

9. Mfr. report number: HQ8164505JUL2000

H. Initial reporter

1. Name & address: [redacted] Jr., [redacted] Suit[redacted] US
phone # [redacted]

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

JUL 07 2000
DATE SENT TO FDA

WYETH AYERST

WYETH-AYERST
BOX 8299
PHILADEL

Individual Safety Report

3626916-X-00-02

MEDWATCH

REPORTING PROGRAM

2

Approved by the FDA on 09/24/1999

Mfr report #	HQ8164505JUL2000
UF/Dist report #	
	FDA Use Only

Box B.. ...ribe event or problem (Continuation)

ulcerative lesions of rather nonspecific character. Such lesions have been described in association with non-steroidal anit-inflammatory drugs, as this patient has been reported to have taken". Patient was discharged from the hospital on 02-Aug-1999.

Box B.6 - Relevant test/laboratory data, including dates (Continuation)

Test Name / Date	Result	Normal Range
Urine analysis 07/20/1999	bloody urine	-
White blood cell count 07/20/1999	elevated	-

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

Therapy Name	Dose, frequency, & route used	Therapy Dates
UNSPECIFIED ESTROGEN REPLACEMENT THERAPY	unknown	unknown
UNSPECIFIED VITAMINS	unknown	unknown

JUL 10 2000

DSS

JUL 11 2000