

# **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



16-JUN-1998-0592

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

Page 1 of 1

Individual Safety Report



\*3094136-8-00\*

85120

A. Patient Information

1. Patient Identifier | 2. DOB: [REDACTED] | 3. Sex | 4. Weight  
[REDACTED] | AGE: 76 yrs | MALE | 92.0 kg

B. Adverse Event or Product Problem

1.  Adverse Event  Product problem

2. Outcomes attributed to adverse event

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

3. Date of event  
04/05/98

4. Date of this report  
06/02/98

5. Describe event or problem  
UGI BLEED

C. Suspect Medication(s)

1. Name  
#1: KETOPROFEN (OTC per pt. md)

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

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

7. Other relevant 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

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

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

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

Med.

(OTC per pt. md)

REC'D.

JUN 16 1998

MEDWATCH CTU

OTC per pt. md

85120

RECEIVED AT DRUG SAFETY SURVEILLANCE



16-JUN-1998-0593

SUSPECT MEDICATION

Individual Safety Report



\*3094136-8-00\*

86120

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

TEST: OHGB RESULTS: 13.3 gm/dL H:18/L:12 COLLECTION DATE: 4/5/98@19:43

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 100A  
MEDWATCH CTU

85120



29-APR-1998-0647

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by contributors: 1AND

Page

Individual Safety Report



1086 )

\*3160487-1-00-01\*

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

FDA Use Only

Patient information

1 Patient identifier	2 Age at time of event: -NI or Date of birth: -NI	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight -NI lbs -91 kgs
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B. Adverse event or product problem

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

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

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

3 Date of event (mo/day yr) 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.

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 unknown

#2 -NA

3 Therapy dates (if unknown, give duration)

#1 from to (or best 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  doesn't apply

#2  yes  no  doesn't apply

6 Lot # (if known)

#1 Unknown

#2 -NA

7 Exp. date (if known)

#1 -NA

#2 -NA

8 Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

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

0573 - 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 #

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

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

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

yes  no  returned to manufacturer on

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

E. Initial reporter

1 Name, address & phone #

[Redacted] Blvd. suite [Redacted] United States

2 Health professional?  
 yes  no

3 Occupation  
-NA

4 Initial reporter also sent report to FDA  
 yes  no  unk



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

MS 4/17/98  
720442218  
6/24/98

00-0019

WYETH  
BOX 825  
PHILADI

WYETH Individual Safety Report



**MEDWATCH**

'S REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ8164505JUL2000

UF/Dist report #

FDA Use Only

if 2

**A. Patient information**

1. Patient identifier [REDACTED] in confidence	2. Age at time of event: or UNK Date of Birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK or lbs or kgs
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**B. Adverse event or product problem**

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

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

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



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

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

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

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

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

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

**G. All manufacturers**

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

2. Phone number  
6109024647

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

4. Date received by manufacturer (mo/day/yr)  
07/03/2000

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

6. If IND, protocol #

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

8. Adverse event term(s)  
Colon anterior resection  
Gastritis NOS  
Gastric ulcer  
DS:3  
JUL 11 2000

9. Mfr. report number  
HQ8164505JUL2000

**E. Initial reporter**

1. Name & address  
Jr., Suite  
US

2. Health professional?  
 yes  no

3. Occupation

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

FDA Form 3500A (facsimile)  
JUL 07 2000  
DATE SENT TO FDA

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



\*3526918-X-00-02\*

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

Box B. Describe event or problem (Continuation)

ulcerative lesions of rather nonspecific character. Such lesions have been described in association with non-steroidal anti-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