Individual Safety Report

3583058-1-00-01

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Form Approved: OMB No 0910-0291 Expires 12/31/9
See OMB statement on reverse

FDA Use Only H Pad

Triage unit sequence # 129840

Page ___ of ___

6 Dev
CDER

A. Patient information

1. Patient identifier: [redacted]0507 in confidence
2. Age at time of event: 48 YO or Date of birth: [redacted]
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or 105 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): 3/4/00
4. Date of this report (mo/day/yr): 3/10/00
5. Describe event or problem

pt admitted c̄ kidney stone. Pt had been taking Darvocet-N100's for pain. Pt had been taking ~ 12 Darvocet daily and developed liver toxicity. After Darvocet held pt's liver toxicity resolved.

6. Relevant tests/laboratory data, including dates

AST-393, ALT-89, T bili - 4.5 on admit.

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

DSS

SEP 29 2000

IV129840

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Propoxyphen / APAP - 650 mg
   #2
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
   #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)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
   VA Med Center
   1000 Locust - Reno, NV 89502
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