Individual Safety Report

3724563-4-00-01

FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by professionals of adverse
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 # 143632

A. Patient information

1. Patient identifier: [redacted] 72/16 — In confidence
2. Age at time of event: or Date of birth: 11/20/78
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): 12/27/00
4. Date of this report (mo/day/yr): 12/28/00
5. Describe event or problem

22 YOF pres to OSH ED 12/27 AM w/ abd pain, nausea, feeling sick. Had abn LFTs & adm. to taking 7 gm APAP over 12 H period on 12/26 for menstrual cramps (1.5 gm 0800, 1.5 gm 1200, 2 gm 1700, 2 gm 2300). IRX w/ charcoal/acetylcysteine and adm to ICU. Cont'd to deteriorate and tx'd here with acute fulminant hepatic failure. Questionable alcoholism; hx binge drinking at 12 YO. Had 2 drinks on 12/24, 5 beers on 12/22. Avg consumption about 2 cases beer/mo. LFTs 12/28: ALT 4600; AST 12626; LDH 67676; AlkPhos 112; GGT 156; Tbili 3.5; INR 3.2. By 1/1/01, transaminases resolving, Tbili and GGT still inc. Evid of past

6. Relevant tests/laboratory data, including dates

LFT's 12/28:
ALT 4600
AST 12626
LDH 67676
Alk Ø 112
GGT 156
Ammonia 30

Tbili 3.5
INR 3.2

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

NKDA
h/o EtOH abuse

CTU 143632

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Acetaminophen
   #2
2. Dose, frequency & route used
   #1 12/26 1.5gm 0800, 1.5gm 1200, 2gm 1700, 2gm 2300
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 12/26
   #2
4. Diagnosis for use (indication)
   #1 menstrual 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)

none

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)

DSS
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MEDWATCH CTU

E. Reporter (see confidentiality section on back)

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

FDA

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

or FAX to:
1-800-FDA-0178