CDER

Individual Safety Report

3620825-X-00-01

VOLUNTARY reporting
lth professionals of adverse
nts and product problems

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

FDA Use Only

Triage unit sequence # 133475

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CDER

A. Patient information

Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	31 12/7/68	☒ female ☐ male	130 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): Before 10/30/00

4. Date of this report (mo/day/yr): 12/4/00

5. Describe event or problem

Pt (31yo F) w/ PMH of EtOH abuse. Vomiting 4 days prior to admission. C/o severe abdominal pain. Had been taking Tylenol PM 3-4 times a day. ↑ EtOH intake in past 3 months due to personal stressors. Admitted for evaluation of acute hepatitis. Patient received Mucomyst and IV fluids. Pt d/c'd in stable condition.

Relevant tests/laboratory data, including dates

SGPT >15,000 (10/30/00) → 323 (10/6)
SGPT = 9386 (10/30/00 → 81 (11/6)
APAP level = 34.1 (10/30/0)
= 6.9 (10/31)

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

EtOH use
?? Depression

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

C. Suspect medication(s)

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

2. Dose, frequency & route used
#1 3-4 times/day
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 ~~[illegible]~~ Before 10/30/00
#2

4. Diagnosis for use (indication)
#1 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)

DEC 04 2000

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: ___

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)

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. ☐

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

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or FAX to: 1-800-FDA-0178

3500 (6/93)

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

CTU 133475