AUG- 4-99 WED 9:46 [redacted] PHARMACY FAX NO. [redacted] P. 02

Individual Safety Report

3318081-5-00-01

CDER

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

LUNTARY reporting by health professionals of adverse events and product problems

CDER

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

FDA Use Only (MB)

Triage unit sequence # 107822

A. Patient information

1. Patient identifier: 833469 in confidence
2. Age at time of event: 16 or Date of birth: [redacted]
3. Sex: [x] female [ ] male
4. Weight: 133 lbs or ___ kgs

B. Adverse event or product problem

1. [x] 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
   - [x] hospitalization initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [x] required intervention to prevent permanent impairment/damage
   - [ ] other: ___
3. Date of event (mo/day/yr): 6-2-99
4. Date of this report (mo/day/yr): 6-25-99
5. Describe event or problem

THIS 16 YOF INGESTED 29 (500mg) TYLENOL PILLS ON 6-1-99 TO INDUCE NAUSEA/VOMITING (PURGE) HERSELF WHICH SHE HAD BEEN DOING FOR 5-7 DAYS. SHE DEVELOPED ABD. PAIN, N/V & WAS SUBSEQUENTLY BROUGHT IN FOR EVALUATION. LIVER INDICES WERE ELEVATED AS INDICATED BELOW. SHE WAS TREATED SYMPOTHATICALLY & WITH ACETYLCYSTEINE (17gms, THEN 3.7gms FOR A TOTAL OF 17 DOSES) THE PATIENT WAS EVENTUALLY DISCHARGED IN RELATIVELY GOD CONDITION WITH ENZYMES WHICH WERE DECREASING & A FOLLOW-UP APPOINTMENT IN ONE WEEK AFTER DISCHARGE.

6. Relevant tests/laboratory data, including dates

	6/2	6/3	6/4	6/5
WBC	12.1			
PT/INR	13.3/1.26		14.3/1.36	13.3/1.26
AST	71	393	1312	258
ALT	65	328	1459	798
T bil.	1.7	2	1.4	1.1
APAP	11.0			

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

NONE

CTU 107322

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 ACETAMINOPHEN EXTRA STRENGTH
   #2
2. Dose, frequency & route used
   #1 500mg (14.5gms) PO
   #2
3. Therapy dates (if unknown, give duration) (mo/day/yr or best estimate)
   #1 6-1-99
   #2
4. Diagnosis for use (indication)
   #1 TO INDUCE NAUSEA/VOMITING
   #2
5. Event abated after use stopped or dose reduced
   #1 [x] 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 [x] 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

REC'D.

4. Operator of device
   - [ ] health professional
   - [ ] lay user/patient
   - [ ] other: ___
5. Expiration date (mo/day/yr)
6. model # AUG 05 1999
   catalog # ___
   serial # MEDWATCH CTU
   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] HOSPITAL PHARMACY
   [redacted]

DSC AUG 0 5 1999

2. Health professional? [x] 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.

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