



UNITARY reporting professionals of adverse events and product problems CDER

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

FDA Use Only
Trace unit sequence # 127629

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information

1. Patient identifier: 4754
2. Age at time of event: [redacted] Date of birth: [redacted]
3. Sex: female male
4. Weight: [redacted] lbs or [redacted] 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 (mortality)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event (m/d/yyyy): 3/5/00
4. Date of this report (m/d/yyyy): 3/8/00

5. Describe event or problem
a0e_id: 4754
adr_desc: 16 YOF underwent root canal on 3/3. Afterwards, pt ingested 16 tabs of Acetaminophen 500 MG between 1600 and 2330 on 3/4. On 3/5 at 0130, pt awoke with acute RUQ pain, N/V. Pt adm to ED and RX for Acetaminophen toxicity with Mucomyst. Pt adm to floor for further eval. Pt had elev in LFT and Tbil 1.3. APAP level on admission at 41.3.

6. Relevant tests/laboratory data, including dates
Tbili = 1.3
APAP level = 41.3 > 12° p ingestion

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
Allergies = Ampicillin (swbc)
PMH = sclerosing cholangitis

CTU 127629



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Acetaminophen
#2
2. Dose, frequency & route used
#1 8gm in 7.5 hrs.
#2
3. Therapy dates (if unknown, give duration)
#1 3/5/00
#2
4. Diagnosis for use (indication)
#1 dental 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)
Actigall 900mg po qhs

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address: AUG 23 2000
4. Operator of device: health professional lay user/patient other:
5. Expiration date (m/d/yyyy): AUG 22 2000
6. model #
7. If implanted, give date (m/d/yyyy)
8. If explanted, give date (m/d/yyyy)
9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on (m/d/yyyy)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone # [redacted] PharmD
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.