Individual Safety Report

372953?-6-00-01

For VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

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

FDA Use Only

Triage unit sequence # 144419

Page ___ of ___

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted]461 In confidence	or ___ Date of birth: 7/29/42	☒ female ☐ male	___ lbs or 36 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): 4/27/01

4. Date of this report (mo/day/yr): 5/1/01

5. Describe event or problem

58 YOF with PMH for COPD, diet-controlled DM, 40lb weight loss over 6 mos, ETOH abuse was found to be acting "wild and agitated" by neighbor. 911 called. In ED, BS=32, BP 83/72, HR 143, T 95, AST=6906, ALT=5572, Alk Phos=78, Tbili=3.0, INR=4.8, PT=26.3, SCr=1.5, Anion gap= 35, APAP=61.2. Pt reported taking APAP for GI pain. Other etiologies ruled out. Hep B surface AB (+). Pt adm to MICU, acetylcysteine x 17 doses started. Pt developed worsening encephalopathy and hypercapnia. Pt intubated on 4/28 for airway protection, APAP=24.6. On 4/30, LFTs: AST=2665, ALT=5184, Alk

6. Relevant tests/laboratory data, including dates

	APAP	AST	ALT	Alk Ø	T Bili	PT
4/27	61.2 36.5	6906	5572	78	5	26.3
4/28	24.6	9254	7532	76	3.4	27
4/29		9420	9474	107	4.6	26.2
4/30		2665	5184	97	6.0	24.3

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

PMH:
DM
COPD
PUD
Depression (2-3 past suicide attempts)
?S/P CVA
Dementia

Allergy: codeine

C. Suspect medication(s)

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

2. Dose, frequency & route used
   #1 UNK PO
   #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 4/27 + before
   #2

4. Diagnosis for use (indication)
   #1 abdominal 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)
Darvocet, codeine (?), albuterol, atrovent, theophylline

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: ___

RECEIVED
MAY 29 2001
MEDWATCH CTU

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 or FAX to: 1-800-FDA-0178

FDA

Form 3500 (6/93)

Site 144419

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