Individual Safety Report

3464106-6-00-01

Page ___ of ___ CDER Dell 117785

[redacted]8864 | Age at event: or 57 | Date of birth: 10/9/42 | ☐ female ☒ male | 4. Weight: ___ lbs or 119.3 kgs

In confidence

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 ___ (mm/dd/yyyy)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ___

3. Date of event (mm/dd/yyyy): 02/09/00

4. Date of this report (mm/dd/yyyy): 02/12/99

5. Describe event or problem

Patient presents to hospital c worsening 2 month hx of dyspnea, 3+ pedal edema, and abdominal distention. The patient states that he drinks ~ 10 beers/day and has been taking 8-12 500mg tabs of Tylenol daily for the last 2 months for a headache that will not go away. He states that the Tylenol only "numbs" the headache, but never relieves it.

PE: ascites, 3+ edema and fever probably due to alcoholic hepatitis and cirrhosis.

R/o: spontaneous bacterial peritonitis + chronic Tylenol toxicity.

A: acute/chronic deterioration of liver function 2° to ETOH abuse, possible due to Tylenol ingestion

6. Relevant tests/laboratory data, including dates

Acetaminophen level 2/9/00 = 10.7

Gram stain: neg.

2/10/00 Albumin 1.8, SGOT 99, Bili 7.7 Scr 1.1, BUN 10, INR 1.6

2/11/00 Albumin 1.7, SGOT 97, Bili 10.3 Scr 0.9, BUN 11, INR 1.5

2/12/00 Albumin 2.2, SGOT 75, Bili 9.6 Scr 1.0, BUN 14, GGT 457

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

Type II DM x 1.5 yrs

HTN x 1.5 yrs

ETOH Detox 1998

Allergies: PCN + cephalosporins = hives

DSS

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Tylenol 500mg
   - #2

2. Dose, frequency & route used
   - #1 500mg 8-12 tabs PO daily x 2 months
   - #2

3. Therapy dates (if unknown, give duration)
   - #1 Dec 99 - Feb 00
   - #2

4. Diagnosis for use (indication)
   - #1 Relief of persistent HA
   - #2

5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☐ does apply
   - #2 ☐ yes ☐ no ☐ does apply

6. Lot # (if known)
   - #1 —
   - #2 —

7. Exp. date (if known)
   - #1
   - #2

8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ does apply
   - #2 ☐ yes ☐ no ☐ does apply

9. NDC # (for product problems only)
   - —
   - —

10. Concomitant medical products and therapy dates (exclude treatment of event)

Lisinopril 5mg 1 QD
Trazodone 50mg 2 HS
Glyburide 5mg 1 BID
Furosemide 20mg 1 QD PRN LE edema
Vit E 400 units QD
Vit B, Vit C 1 QD

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: ___

5. Expiration date (mm/dd/yyyy)

6. model # ___ catalog # ___ serial # ___ lot # ___ other # ___

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone

[redacted] Ph

Department of Veterans Affairs
Pharmacy Service (119)
Fort Harrison, Montana 59636

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacy

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.

CTU 117785