Individual Safety Report

3180108-1-00-01

For VOLUNTARY reporting health professionals of adverse events and product problems

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A. Patient information

1. Patient identifier: 4422 (in confidence)
2. Age at time of event: 49 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: 148 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 ___ (mm/day/yr) ☐ life-threatening ☒ hospitalization – initial or prolonged ☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other
3. Date of event (mm/day/yr): 8/14/98
4. Date of this report (mm/day/yr): 9/29/98
5. Describe event or problem:

49 yo m with h/o poly-substance abuse + hepatitis txed with oxazepam for insomnia which contributed to worsening of mental status. Pt transferred to ICU for seizure disorder + worsening hepatic encephalopathy. Pt txed w/ lactulose + mental status improved.

6. Relevant tests/laboratory data, including dates

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr labeler if known)
   #1 Oxazepam 30mg Q HS pm
   #2 APAP 500mg QID pm
2. Dose, frequency & route used
   #1 OXAZEPAM
   #2 TYLENOL
3. Therapy dates (if unknown, give duration)
   #1
   #2
4. Diagnosis for use (indication)
   #1 insomnia
   #2 pain
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)

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
5. Expiration date (mm/day/yr)
6. model # ___ catalog # ___ serial # ___ lot # ___ other # ___
   MEDWATCH CTU
7. If implanted, give date (mm/day/yr)
8. If explanted, give date (mm/day/yr)
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   VA MEDICAL CENTER (847) 688-1900 x3750
   Pharmacy Service (119) LINDA LANE, RPH
   3001 GREEN BAY ROAD
   NORTH CHICAGO, IL 60064
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. ☐

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 95769 possible ADR

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ADR CONTINUATION REPORTING SHEET

PATIENT: _____

PAST MEDICAL HISTORY	49 yo m with polysubstance abuse h/o hepatitis B and C (antibodies present)
MEDICATIONS UPON ADMISSION	Oxazepam 30mg @ HS prn (started 7/29/98) APAP 500 mg TID prn pain (h/o long-term use)
PHYSICAL EXAM	BP / TEMP / PULSE / RESP / OTHER PT. INFO
EKG	

LABS	AST	ALKPHOS	Bilirubin (T)	Gamma GTP	PLT
8/10/98	169	195	2.5	110	74 X 1000
	(15-37)	(50-136)	(0-1)	(5-85)	(148-348)

SEQUENCE OF EVENTS	
	7/29/98 - Pt on B1-4C - c/o insomnia. Start Oxazepam 30mg @ HS prn. Also pt on Tylenol 500 TID prn pain. Pt c/o excessive sleepiness - Oxazepam d/c'd

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PATIENT:

SEQUENCE OF EVENTS

8/4 - Pt c/o insomnia again + asked that Oxazepam be reinstated
Oxazepam resumed

8/6 - Pt confused, ataxic, disoriented
A/P - encephalopathy probable metabolic vs drug-induced
Oxazepam D/Cid + Acetaminophen D/Cid
8/10 - pt more alert
8/12 - scleral icterus present
start lactulose 30 ml TID
pt had grand mal seizure - unresponsive x 10 min - transfer to ICU
start Dilantin IV
CT scan negative - no electrolyte Abnormality

8/14 - pt still lethargic, confused, slurred speech
A/P - hepatic encephalopathy - Stage I
Given Ativan 2mg IM after he wandered off ward + placed in Pusey + restraints

8/20 - pt oriented x 3
hepatic encephalopathy stable
transfer to 125 CD
GT f/u + liver biopsy planned -

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