Individual Safety Report

3439991-4-00-01

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

Page CDER

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

FDA Use Only (MSB)

Triage unit sequence # 115046

A. Patient information

1. Patient identifier: 0079 In confidence
2. Age at time of event: 43 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ 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 (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): 7/4/99
4. Date of this report (mo/day/yr): 11/30/99
5. Describe event or problem

N, V, ↑LFTs, RuQ pain
Treated ε Acetylcysteine. 7/4+7/5

Patient limited more severely in vicodin intake

6. Relevant tests/laboratory data, including dates

	SGOT	LDH	Alk P	GPT	T.Bil
7/4	101	369	89	72	1.9
7/5	118	341	56	69	1.2
7/6	109	271	58	88	.6

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

DSB patient

JAN 7 '00 AM 9:22

CTU 115046

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Vicodin
   #2
2. Dose, frequency & route used
   #1 unknown but excessive
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 → 7/4/99
   #2
4. Diagnosis for use (indication)
   #1 Arth-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)

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 (mo/day/yr)
6. model #
   catalog #
   serial #
   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)

DSS
JAN 07 2000
ADVERSE EVENT REPORTING SYSTEM
REC'D.
JAN 07 2000
MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
   VA HOSPITAL (119)
   7400 MERTON MINTER BLVD.
   SAN ANTONIO, TX 78284
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharm D
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