Individual Safety Report

3636446-9-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31/00
See OMB Statement on reverse

FDA Use Only

Triage unit sequence # 134627

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A. Patient information

1. Patient identifier: 688 — In confidence
2. Age at time of event: or Date of birth: 11/23/51
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): 12/4/99
4. Date of this report (mo/day/yr): 12/7/00
5. Describe event or problem

↑LFT's

Acute Mental Status Changes

6. Relevant tests/laboratory data, including dates

Acetaminophen level = 25.5

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

h/o hepatitis C

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Lortab
   #2
2. Dose, frequency & route used
   #1 55 tabs over 3d
   #2
3. Therapy dates (if unknown, give duration) (mo/da/yr or best estimate)
   #1 12/2/99 - 12/4/99
   #2
4. Diagnosis for use (indication)
   #1 low back 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

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4. Operator of device: ☐ health professional ☐ lay user/patient ☐ other:
5. Expiration date (mo/day/yr)
6. model # / catalog # / 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)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   VA Palo Alto Health Care System
   Pharmacy Service (119)
   3801 Miranda Avenue
   Palo Alto, CA 94304
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.

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