DEC 7 1999 11:49Y

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'OLUNTARY reporting
lth professionals of adverse
nts and product problems

CDER

NO. 374 Approved P. 1/1

FDA Use Only

Triage unit sequence # 113789

E FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: or 35 y/o; Date of birth: Unknown
3. Sex: ☒ female ☐ male
4. Weight: N/A lbs or N/A 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. Date of this report (mo/day/yr)
5. Describe event or problem

Adult pt was receiving Vicodin 2 tablets Q4h pm for chronic back pain. Prior to admission pt had excessive ingestion and admitted with liver tox.

DSS

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ADVERSE EVENT REPORTING SYSTEM

6. Relevant tests/laboratory data, including dates

No specific # available But LFTS ordered as standard of care

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

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Vicodin ES [redacted]
   #2
2. Dose, frequency & route used
   #1 2 tables Q4h pm
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 Chronic therapy
   #2
4. Diagnosis for use (indication)
   #1 Muscoketal 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 # REC'D.
   catalog # DEC 07 1999
   serial #
   lot # MEDWATCH CTU
   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 #
   [redacted] PharmD Center Thop [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Clinical RPh
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 113789