Individual Safety Report

3731968-4-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
health professionals of adverse
events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 11/30/
See OMB statement on revers

FDA Use Only

Triage unit sequence # 144678

A. Patient information

1. Patient identifier: In confidence
2. Age at time of event: 49 or Date of birth:
3. Sex: [ ] female [X] male
4. Weight: 72 lbs or ____ kgs

B. Adverse event or product problem

1 [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)
- [ ] death ____ (mo/day/yr)
- [X] life-threatening
- [X] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other: ____

3 Date of event (mo/day/yr): 5/23/01

4. Date of this report (mo/day/yr): 5/25/01

5 Describe event or problem

VICODIN USED OUTPATIENT FOR BACK PAIN. FOUND BY FAMILY UNCONCIOUS, ELEVATED ACETAMINOPHEN LEVEL ON ADMISSION, COAGULOPATHIC, AND UNRESPONSIVE TO NARCAN

DIAGNOSIS → FULMINANT HEPATIC FAILURE C HEPATIC ENCEPHALOPATHY

6 Relevant tests/laboratory data, including dates

5/23/01 PT/INR 33.7/6.5
5/23/01 PTT 48.2
5/23/01 BILI/BILI DIRECT 4.1/1.8
AST/ALT 7428/6474
5/23/01 ACETAMINOPHEN 46.3

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

FORMER FOR OPIATE ADDICT
2 COCAINE INDUCED MI'S IN PAST?
CURRENTLY IN REMISSION

CTU 144678

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler if known)
#1 VICODIN
#2

2. Dose, frequency & route used
#1 UNKNOWN
#2

3. Therapy dates (if unknown, give duration) (from/to or best estimate)
#1 UNKNOWN
#2

4. Diagnosis for use (indication)
#1 BACK PAIN?
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [X] no [ ] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1 UNKNOWN
#2

7. Exp. date (if known)
#1 UNKNOWN
#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)
UNKNOWN

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 # RECEIVED
catalog # JUN 01 2001
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 ____

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

E. Reporter (see confidentiality section on back)

1. Name & address: phone [redacted]

2. Health professional? [X] 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