Individual Safety Report

3735565-6-00-01

OLUNTARY reporting
lth professionals of advers
its and product problems

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

FDA Use Only
145000
Triage unit sequence #
OPDRA Karwoski
faxed to [redacted]

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A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 45 or Date of birth: 12-22-55
3. Sex: [ ] female [X] male
4. Weight: ___ lbs or 58 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)
   - [X] death 5-7-00 (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): 5-4-00
4. Date of this report (mo/day/yr): 5-14-01
5. Describe event or problem

Elevated LIver enzymes.
Esophageal varicies
Admit vomiting bright red fluid
Coded 5-6-00. Went into acute renal failure, hepatorenal syndrome.
Asystole 5-7-00.

6. Relevant tests/laboratory data, including dates

5-4-00 Acetaminophen serum level= 74
AST 14499 (normal is 37)
ALT 2595 (normal is 20-65)
ALK Phos 211 (normal is 50-136)
Platelets= 0
Blood sugar = 419

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

Hx: IDDM
Prolonged history of alcoholism
chronic pancreatitis

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Nyquil (acetaminophen)
   #2
2. Dose, frequency & route used
   #1 1 bottle / day
   #2 = 3683mg acetaminophen
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 last 6 days PTA
   #2
4. Diagnosis for use (indication)
   #1 Upper respiratory infection
   #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
   #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)

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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)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]

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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. [X]

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.