Individual Safety Report

3255048-X-00-01

FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

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

FDA Use Only

Triage unit sequence # 102386

A. Patient information

1. Patient identifier: 4476421 in confidence
2. Age at time of event: 42 or Date of birth: 6-21-56
3. Sex: [X] female [ ] male
4. Weight: ___ lbs or 68 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
   - [X] required intervention to prevent permanent impairment/damage
   - [ ] other:
3. Date of event (mo/day/yr): 1-23-99
4. Date of this report (mo/day/yr): 5-6-99
5. Describe event or problem

pt admitted from another hospital with liver and renal failure - pt was taking Fluconazole + Percocet - pt liver enzymes ↑ - pt fulminant hepatic failure - transferred to another hospital for liver transplant

1-15 liver enzymes normal

6. Relevant tests/laboratory data, including dates

1-22 transaminases 21 010 INR 7.37
AST - 5574 Ammonia 121
Alt 5898 Tylenol level = 38
Amylase 352
Lipase 3618
LDA 10273 ArG = 4.4

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

black female history of treatment pituitary tumor 2° hypothyroidism and hypopituitarism smoker

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Fluconazole FLUCONAZOLE
   - #2 Percocet PERCOCET
2. Dose, frequency & route used
   - #1 200mg po gd
   - #2 1cmg po gd
3. Therapy dates (if unknown, give duration) (mo/day/yr or best estimate)
   - #1 1-15- 1-19-99
   - #2 1-19- —
4. Diagnosis for use (indication)
   - #1 fungal infection
   - #2 pain
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 DSS
3. Manufacturer name & address
   MAY 0 6 1999
   ADVERSE EVENT REPORTING SYSTEM
4. Operator of device
   - [ ] health professional
   - [ ] lay user/patient
   - [ ] other:
5. Expiration date (mo/day/yr)
6. model # REC'D.
   catalog # MAY 0 6 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 [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation: Pharmacist
4. Also reported to
   - [ ] manufacturer
   - [ ] user facility
   - [ ] distributor

If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [ ]

PLEASE TYPE OR USE BLACK INK

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20858

MEDWATCH
FDA MEDICAL PRODUCTS REPORTING PROGRAM
HF-2

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 102386