Individual Safety Report

3497858-X-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
health professionals of adverse
events 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 H Pad

Triage unit sequence # 121946

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 43 or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: 113 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)
- [ ] life-threatening
- [ ] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [X] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of event (mo/day/yr): 4/30/00
4. Date of this report (mo/day/yr): 5/5/00

5. Describe event or problem

Patient admitted i Pancreatitis on 4/29/00 4/30/00 = Darvocet N100 1-2 to 6 3 q 4-6 ordered for pain of pancreatitis. From Darvocet, daily acetaminophen given: 4/30/00 = 5850mg, 5/1/00 = 5200mg, 5/2/00 = 1950mg. Patient experienced ↑ liver enzymes and ↑ PTT/INR.

6. Relevant tests/laboratory data, including dates

	4/29/00	4/30/00	5/1/00	5/2/00	5/3/00	5/4/00	5/5/00	5/6/00	5/7/00	5/8/00
LK Fitase	242		143	150	165	184	165	174	169	
ST	22			13460	13480	15800		8790	2990	
ALT	35		72	5140	5150	6190	6400	5970	4450	
1. Total				1.1	1.0	1.0			1.4	
2. time							20.3	22.4	18.8	
INR							2.223	2.72	1.91	

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

Allergies – PCN, Codeine
Concussion
Moderate EtOH use!

CTU 121946

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Propoxyphene N/Acetaminophen 100/650mg UDL
#2 Pepcid infusion 1.6mg/hr STC Pharm.

2. Dose, frequency & route used
#1 1-2 q 4-6 Jarn
#2 1.6mg/hr

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 4/30/00 → 5/2/00
#2 4/29/00 → 5/2/00

4. Diagnosis for use (indication)
#1 Pain
#2 Abd. Pain, Pancreatitis

5. Event abated after use stopped or dose reduced
#1 [X] yes [ ] no [ ] doesn't apply
#2 [X] 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 [X] doesn't apply
#2 [ ] yes [ ] no [X] 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 # MAY 0 8 2000
catalog # MEDWATCH CTU
serial #
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)

DSS
MAY 0 9 2000
RECEIVED

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 HF-2 or FAX to: 1-800-FDA-0178
5600 Fishers Lane
Rockville, MD 20852-9787

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.