

Individual Safety Report



VOLUNTARY reporting with professionals of adverse events and product problems Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 12/31/00 See OMB statement on reverse

FDA Use Only

FDU unit sequence #

141312 FAXED to OPRA

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient Identifier [redacted] 2. Age at time of event: 39 Years or Date of birth: 01/29/1961 3. Sex: [x] female [] male 4. Weight: 125 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): [x] death 09/23/2000 [x] life-threatening [x] hospitalization - initial or prolonged [] disability [] congenital anomaly [] required intervention to prevent permanent impairment/damage [] other: 3. Date of event (m/d/yyyy): 09/22/2000 4. Date of this report (m/d/yyyy): 04/11/2001

5. Describe event or problem Sick with flu like symptoms for three days and then became lethargic, combative, and losing recognition of her familiar surroundings, appeared jaundiced, bloated. Had been taking Tylenol and Vicodin for chronic knee problems; flank pain.

6. Relevant tests/laboratory data, including dates Before this event there was no lab work done. At the ER she had labs for liver enzymes, CAT scan, spinal tap, drug screen, showing AST and ALT tests of 12,000 and 14,000 respectively.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) White female, non smoking, allergic to Asparagus. Had complained of flank pain for several months, but was not tested for anything specific.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler) #1 Hydrocodone/APAP / 7.5/650 mg #2 Tylenol / 500 mg 2. Dose/Frequency/Route used #1 1 or 2 / 4 hours / Oral #2 2 / 4 hours / Oral 3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 09/07/1996 - 09/17/2000 #2 09/07/1994 - 09/17/2000 4. Diagnosis for use (separate indications with commas) #1 Chronic knee pain; Flank pain #2 Chronic knee pain; flank pain 5. Event abated after use stopped or dose reduced #1 [] yes [x] no [] doesn't apply #2 [] yes [x] 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) 5244-0502-01 - 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 (m/d/yyyy) 6. model # MEDWATCH CTU catalog # serial # lot # other # 7. If implanted, give date (m/d/yyyy) 8. If explanted, give date (m/d/yyyy) 9. Device available for evaluation? (Do not send device to FDA) [] yes [] no [] returned to manufacturer on (m/d/yyyy) 10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted] 2. Health professional? [x] yes [] no 3. Occupation Other Health Professional 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. []



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.