



* indicates item continued

A. Patient Information

1. Patient Identifier confidence
 2. Age at time of event: 42 YRS
 or Date of Birth: [redacted]
 3. Sex Female Male
 4. Weight 125.0lbs or kgs

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 # 1 ZITHROMAX CAPSULES
 # 2 TYLENOL #3
 2. Dose, frequency & route used
 # 1 250.00 MG TOTAL DAILY ORAL
 # 2 NOT SPECIFIED
 3. Therapy dates (if unknown, give duration from to (or best estimate))
 # 1 06/21/99 - 06/--/99
 # 2 UNKNOWN
 4. Diagnosis for use (indications)
 # 1 INFECTION PROPHYLAXIS
 # 2 PAIN
 5. Event abated after use stopped or dose reduced
 UNKNOWN do not apply
 # 1 yes no apply
 # 2 yes no apply
 6. Lot # (if known)
 # 1 UNKNOWN
 # 2 UNKNOWN
 7. Exp. date (if known)
 # 1 UNKNOWN
 # 2 UNKNOWN
 8. Event reappeared after reintroduction
 UNKNOWN do not apply
 # 1 yes no apply
 # 2 yes no apply
 9. NDC # - for product problems only (if known)
 N/A
 10. Concomitant medical products and therapy dates (exclude treatment of event)
 NONE

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g. defects/malfunctions)
 2. Outcomes attributed to adverse event (Check all that apply)
 death (mo/day/yr) disability
 life-threatening congenital anomaly
 hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage
 other:
 3. Date of event 06/27/99 (mo/day/yr)
 4. Date of this report 12/21/99 (mo/day/yr)

5. Describe event or problem
 THIS REPORT IS BASED ON INFORMATION RECEIVED BY PFIZER ON 21SEP99, 13JUL99, AND 26AUG99. THIS 42 YEAR OLD FEMALE NURSE REPORTS STARTING ZITHROMAX (AZITHROMYCIN) (Z-PAK) 500MG THE FIRST DAY, FOLLOWED BY 250MG DAILY FOR 4 DAYS AROUND 15MAR99 FOR STATUS POST BONE GRAFT INFECTION PROPHYLAXIS. ON 21JUN99, THE PATIENT HAD A PLANNED DENTAL IMPLANT INTO THE GRAFT AND WAS STARTED ON A SECOND ZITHROMAX Z-PAK THAT SAME DAY FOR INFECTION PROPHYLAXIS. AFTER THE SECOND SURGERY, THE PATIENT WAS PRESCRIBED TYLENOL #3 FOR PAIN (SHE ONLY TOOK A FEW). ON HER FOURTH DAY OF ZITHROMAX THERAPY, 24JUN99, THE PATIENT DEVELOPED SHOULDER PAIN, HEADACHE, WHOLE BODY PAIN, FATIGUE AND A STRONG STABBING PAIN IN THE UPPER RIGHT QUADRANT (URQ) BY THE PANCREAS. THE PATIENT THOUGHT SHE HAD THE FLU. ON 27JUN99, THE PATIENT WAS DRIVING HER CAR AND STARTED TO BECOME VERY DIZZY AND DEVELOPED SEVERE PAIN IN THE UPPER RIGHT QUADRANT AREA AND BROKE OUT IN A TOTAL BODY SWEAT. THE PATIENT DROVE HOME, LAID IN THE GRASS WITH THE PAIN CONTINUING AND WAS SO DIZZY THAT SHE WENT TO THE EMERGENCY ROOM. AFTER THE PATIENT PRESENTED TO THE EMERGENCY ROOM, A COMPUTERIZED AXIAL TOMOGRAPHY WAS DONE, THE RESULTS OF

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G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
 PFIZER REGULATORY SAFETY
 PFIZER PHARMACEUTICALS
 235 EAST 42 STREET
 NEW YORK, N.Y. 10017
 U.S.A.
 2. Phone number 212-573-3129
 3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other
 4. Date received by manufacturer (mo/day/yr) 07/13/99
 5. (A) NDA # NDA #50-670
 IND #
 PLA #
 pre-1938 yes
 OTC product yes
 6. Adverse event term(s)
 HEPATITIS

6. Relevant tests/laboratory data, including dates
 27JUN99: COMPUTERIZED AXIAL TOMOGRAPHY, RESULTS UNKNOWN.
 27JUN99: LIVER ENZYMES, "VERY ELEVATED".
 26JUN99: LIVER ENZYMES IN THE 1000'S, HEPATITIS SCREENING FOR TYPES A, B AND C - ALL NEGATIVE.
 JUL99: LIVER ENZYMES HAVE COME DOWN, BUT ARE STILL ELEVATED.
 SGOT = 368, SGPT = 298, ALKALINE PHOSPHATASE = 94, TOTAL BILIRUBIN = 0.4, CBST = 658, SCPT = 1038.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)
 OBSESSIVE COMPULSIVE DISORDER
 GALL BLADDER REMOVED (26JUN99)
 IRITABLE BOWEL SYNDROME
 CHOLESTEROL DISORDER (UNSPECIFIED);
 ZITHROMAX (AZITHROMYCIN) USE
 TYLENOL #3 (ACETAMINOPHEN, CODEINE) USE
 BONE GRAFT
 - BONE GRAFT INFECTION PROPHYLAXED WITH ZITHROMAX (AZITHROMYCIN)

E. Initial reporter

1. Name, address & phone #
 [redacted]
 2. Health professional? yes no
 3. Occupation NURSE
 4. Initial reporter also sent report to FDA
 yes no unk



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 3932140

B5. EVENT DESCRIPTION - Continued

WHICH ARE UNKNOWN. LIVER FUNCTION TESTS SHOWED THE LIVER ENZYMES TO BE VERY ELEVATED. MAINTENANCE FLUIDS WITH DEXTROSE 5 PERCENT IN WATER WERE STARTED AND THE PATIENT WAS GIVEN DEMEROL (MEPERIDINE) AND VISTARIL (HYDROXYZINE). THE PATIENT WAS LATER RELEASED TO HOME BECAUSE SHE WAS AT THE WRONG HOSPITAL. ON 28JUN99, THE PATIENT WENT TO THE OTHER HOSPITAL AND HER LIVER ENZYMES WERE RECHECKED. THE PATIENT WAS ADMITTED TO THE HOSPITAL AND A HEPATITIS SCREENING FOR TYPES A, B AND C WERE ALL NEGATIVE, BUT THE LIVER ENZYMES WERE IN THE 1000'S. THE LIVER ENZYMES WERE CONTINUALLY MONITORED AND OBSERVED TO KEEP GOING UP. THE PATIENT WAS DIAGNOSED WITH TOXIC HEPATITIS. ON 30JUN99, THE PATIENT WAS DISCHARGED TO HOME. SHE STILL HAS SYMPTOMS OF A HEADACHE, DIZZINESS, BODY PAIN, ORBITS OF EYES ARE PAINFUL AND INDIGESTION. THE PHYSICIAN SUSPECTS THE ZITHROMAX IS RESPONSIBLE FOR THE ADVERSE EVENTS. THE PATIENT'S LIVER ENZYMES HAVE COME DOWN BUT ARE STILL ELEVATED. ADDITIONAL INFORMATION FROM A GASTROENTEROLOGIST STATES THAT THE PATIENT HAD AN ULTRASONOGRAPHY DONE IN ADDITION TO COMPUTERIZED TOMOGRAPHY. SHE HAD A HISTORY OF CHOLESTEROL PROBLEMS. THIS EVENT BEGAN ON 27JUN99, NOT 24JUN99.

ADDITIONAL INFORMATION FROM THE GASTROENTEROLOGIST STATES THAT THE PATIENT ALSO COMPLAINED OF ABDOMINAL PAIN. SHE HAD A HISTORY OF USE OF ZITHROMAX AND TYLENOL #3. TYLENOL #3 ONE GRAM WAS GIVEN TO PROPHYLAX AN ORAL INFECTION. SHE WAS HOSPITALIZED.

E1. NAME AND ADDRESS OF REPORTER - Continued

DR. [REDACTED] CLINIC
 [REDACTED]
 Tel. [REDACTED]
 DR [REDACTED]
 ADDRESS UNKNOWN
 Tel. [REDACTED]

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