

Individual Safety Report



3380741-8-00-01

MED WATCH

FD-304 (Rev. 11-83) MEDICAL PRODUCTS REPORTING PROGRAM

ARM. RES. INST. USA
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

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Approved by FDA on 09/25/99

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|---|
| Mfr report # PRIUSA1999005927 |
| US/Alat report # |
| FDA Use Only |

| | | | |
|--|------------------------------------|---|---------------------------------------|
| A. Patient information | | | |
| 1. Patient identifier ? - ? | 2. Age at time of event 39 yr | 3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male | 4. Weight UNK lbs or UNK kgs |
| In confidence Date of birth: ??/??/?? | | | |
| B. Adverse event or product problem | | | |
| 1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions) | | | |
| 2. Outcomes attributed to adverse event (check all that apply) | | | |
| <input checked="" type="checkbox"/> death ??/??/?? | | <input type="checkbox"/> disability | |
| <input type="checkbox"/> life-threatening | | <input type="checkbox"/> congenital anomaly | |
| <input type="checkbox"/> hospitalization - initial or prolonged | | <input type="checkbox"/> required intervention to prevent permanent impairment/damage | |
| <input type="checkbox"/> other | | | |
| 3. Date of event ??/??/?? | 4. Date of this report 10/19/99 | | |
| 5. Describe event or problem | | | |
| Report published in 1987 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 128). A 39 year-old patient died while taking acetaminophen/codeine and glutethimide. Serum acetaminophen level 19 hours post-ingestion was 39.7 ug/mL. The intent of the ingestion was unknown. | | | |
| Additional information received 12-Oct-99: This 39-year-old female presented to the emergency department in a comatose state, responsive only to painful stimuli. The patient was suspected of ingesting "loads" of acetaminophen with codeine (#3) and glutethimide 19 hours prior to her presentation at the emergency department. The patient was administered 4 mg of naloxone without response. An admission plasma acetaminophen level was 39.7 mcg/mL and the patient was started on an oral regimen of acetylcysteine. At six hours post-admission, the patient was intubated and on a respirator, responsive only to deep painful stimuli, hyperventilating at a rate of 50-60 breaths per minute, and acidotic with a pH of 7.0 and anion gap of 25. | | | |
| (Cont.) | | | |
| 6. Relevant tests/laboratory data, including dates | | | |
| Serum acetaminophen level 19 hours post-ingestion was 39.7 mcg/mL, acidotic with a pH of 7.0 and anion gap of 25, abnormal liver function tests (laboratory tests were unspecified and values were not reported), toxicology screen on urine was positive for glutethimide and acetaminophen | | | |
| 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) | | | |
| unknown | | | |

| | | | |
|---|--|---|--|
| C. Suspect medication(s) | | | |
| 1. Name (give labeled strength & mfr/labeler, if known) | | | |
| #1 TYLENOL WITH CODEINE (tablets) (ACETAMINOPHEN/CODEINE) | | | |
| #2 GLUTETHIMIDE (GLUTETHIMIDE) | | | |
| (Cont.) | | | |
| 2. Dose, frequency & route used | | 3. Therapy dates (if unknown, give duration) | |
| #1 unk, oral | | #1 ??/??/?? | |
| #2 unk, oral | | #2 ??/??/?? | |
| 4. Diagnosis for use (indication) | | 5. Event abated after use stopped or dose reduced | |
| #1 UNKNOWN | | #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply | |
| #2 UNKNOWN | | #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply | |
| 6. Lot # (if known) | | 7. Exp. date (if known) | |
| #1 | | #1 | |
| #2 | | #2 | |
| 8. Event reappeared after reintroduction | | | |
| #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply | | #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply | |
| 9. NDC # - (for product problems only (if known)) | | | |
| 10. Concomitant medical products and therapy dates (exclude treatment of event) | | | |
| No Concomitant Products Reported | | | |

| | | | |
|--|--|---|--|
| G. All manufacturers | | | |
| 1. Contact office - name/address (& mailing site for devices) | | 2. Phone number | |
| R.W. JOHNSON PHARM. RES. INST. USA DIV. OF ORTHO PHARMACEUTICAL CORP. 920 U.S. Route 202 P.O. Box 300 Raritan NJ 08869 USA (Informing Unit) | | 908-704-4504 | |
| 4. Date received by manufacturer (month/year) | | 5. (AINDA # | |
| 10/12/99 | | 85-055 | |
| 6. If IND, protocol # | | IND # | |
| | | | |
| 7. Type of report (check all that apply) | | PLA # | |
| <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1 | | pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes | |
| 9. Mfr. report number | | 8. Adverse event term(s) | |
| PRIUSA1999005927 | | 1) SUDDEN DEATH 2) COMA 3) ANURIA 4) HEPATIC FUNCTION ABNORMAL | |

| | | | |
|---|---------------|--|--|
| E. Initial reporter | | | |
| 1. Name, address & phone # | | | |
| Dr. Toby L. Litovitz National Capital Poison Center Georgetown University Hospital 3800 Reservoir Road NW Washington, DC 20007 USA | | | |
| 2. Health professional? | 3. Occupation | 4. Initial reporter also sent report to FDA | |
| <input checked="" type="checkbox"/> yes <input type="checkbox"/> no | Physician | <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk | |

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

Individual Safety Report



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Continuation Sheet for FDA-3500A Form

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Mfr. report # : PRIUSA1999005927

Date of this report : 10/19/99

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

The patient had received activated charcoal, cathartic, and sodium bicarbonate. Over the next several hours, the patient required multiple doses of sodium bicarbonate and was hemodialyzed. The next day the patient became alert, awake, normalized her acid base disorder, but developed anuria, an enlarged liver and abnormal liver function tests. A toxicology screen on urine was positive for glutethimide and acetaminophen. Later that day the patient expired for unknown reasons. Exposure to medications was acute.

C. Suspect medication (Cont...)

Seq No. : 1
C.1 Suspect medication : TYLENOL WITH CODEINE(tablet)(ACETAMINOPHEN/CODEINE)

Source of report (Literature):

Seq No. : 1
Author : Toby Litovitz
Journal title : American Journal of Emergency Medicine
Year : 88
Edition : 6
Page number : From 479 To 515
Article title : 1987 Annual Report of the American Association of Poison Control Centers National Data Collection System

JCT 25 1999