

Individual Safety Report



13157504-1-00-01

Use by user-facilities, distributors and manufacturers for MANDATORY reporting

Approved by FDA on 10/29/93

Mfr report # 981007-107013869
 UFDist report #
 FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information

1. Patient Identifier UNKNOWN
 2. Age at time of event: 46 Year(s)
 3. Sex female male
 4. Weight _____ lbs or UNK
 _____ kgs
 In confidence Date of birth:

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 22/22/98 (month/day/yr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:
 3. Date of event UNK (month/day/yr)
 4. Date of this report 11/09/98 (month/day/yr)

5. Describe event or problem

Report published in American Journal of Emergency Medicine 16(5), 1997 Annual Report of Poison Control Centers TESS: pp.443-497 (case 260) of a 46 year old, sex unspecified, who ingested acetaminophen with oxycodone due to therapeutic error which resulted in death. Chronicity was acute on chronic. Additional information has been requested.

Follow-up information received 02-NOV-98: This female patient was found unresponsive in the field. Her glucose was zero. She was given glucose and glucagon by medics at the scene. Once in the emergency department she was intubated and provided ventilatory support. Initial evaluation revealed the patient had sickle cell anemia, gastrointestinal bleeding, anion gap metabolic acidosis and was in renal failure and liver failure. She was started on IV N-acetylcysteine. A renal consultation was obtained and hemodialysis instituted within several hours. The patient continued on IV N-acetylcysteine and was transferred to a tertiary care medical center for possible liver transplantation. Patient remained critical and was changed to oral N-acetylcysteine on day 2 of hospitalization. Her neurologic status deteriorated and she died on day three of hospitalization. The patient was using more than the prescribed dose of oxycodone with acetaminophen for pain relief.

6. Relevant tests/laboratory data, including dates

Blood concentration- 107 ug/mL of acetaminophen.
 Follow-up information received 02-NOV-98: initial lab values (date unspecified) WBC 24,000, acetaminophen level 107 mcg/mL, CO2 32, creatinine 3.2, potassium "low", bilirubin 7.2, pH 6.95
 subsequent lab values (date unspecified) SGOT 6140, LDH 9390, BUN 17, creatinine 3.7
 repeat lab values (date unspecified) total bilirubin 3.1, direct bilirubin 1.1, alkaline phosphatase 131, GGT 87, SGOT (Cont.)

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

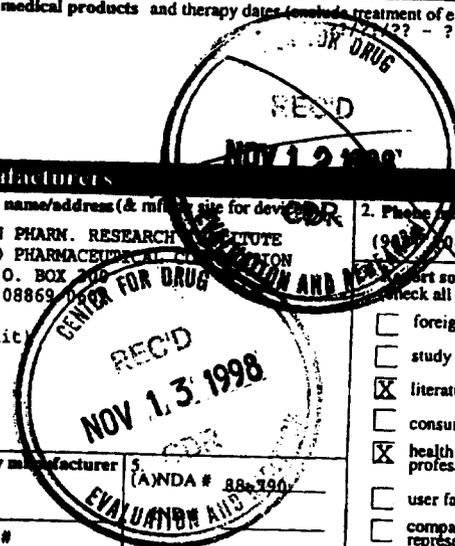
Follow-up information received 02-NOV-98: sickle cell anemia

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 TYLOX CAPSULES (OXYCODONE AND ACETAMINOPHEN)
 #2
 2. Dose, frequency & route used
 Unknown, Unknown, ORAL
 #1
 #2
 3. Therapy dates (if unknown, give duration) (month/year or best estimate)
 #1 Unknown
 #2
 4. Diagnosis for use (indication)
 #1 pain
 #2
 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 UNK
 #2
 7. Exp. date (if known)
 #1 UNK
 #2
 8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply
 9. NDC # - for product problems only (if known)
 NA
 10. Concomitant medical products and therapy dates (include treatment of event)
 1) UNKNOWN

G. All manufacturers

1. Contact office - name/address (& mailing site for device)
 R. W. JOHNSON PHARM. RESEARCH INSTITUTE
 DIV. OF ORTHO PHARMACEUTICALS
 ROUTE 202, P.O. BOX 700
 RARITAN NJ 08869-0700
 (Informing unit)
 2. Phone number
 (908) 394-4600
 3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:
 4. Date received by manufacturer (month/day/yr)
 11/02/98
 5. (A)NDA # 88-190
 6. If IND, protocol #
 7. Type of report (check all that apply)
 5-day 15-day
 10-day periodic
 Initial follow-up # 1
 pre-1938 yes
 OTC product yes



8. Adverse event term(s)

- 1) GI HAEMORRHAGE
- 2) ACIDOSIS
- 3) RENAL FAILURE ACUTE
- 4) HEPATIC FAILURE
- 5) THERAPEUTIC RESPONSE INCREASED
- 6) COMA
- 7) HYPOGLYCAEMIA

E. Initial reporter

1. Name, address & phone #
 TOBY L. LITOVITZ, M.D.
 AMERICAN ASSOC OF POISON CONTROL CENTERS
 3201 NEW MEXICO AVENUE, SUITE 310
 WASHINGTON DC 20016
 Phone #: 202-362-3867
 2. Health professional? yes no
 3. Occupation Physician
 4. Initial reporter also sent report to FDA yes no unk

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

Continuation Sheet for FDA-3500A Form

Mfr. report # : 981007-107013869

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B.6 Relevant tests/laboratory data, including dates (Cont...)

1959, SGPT 1673

Source of report (Literature)

Title	: 1997 ANNUAL REPORT OF THE AMERICAN ASSOCIATION OF POISON CONTROL CENTERS TOXIC EXPOSURE SURVEILLANCE SYSTEM
Author	: TOBY L. LITOVITZ, ET AL
Year	: 1998
Edition	: 16(5)
Journal Title	: AMERICAN JOURNAL OF EMERGENCY MEDICINE
Page No.	: 443 To 497

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3157504-1-00-02

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