

Mfr report #
PRIUSA2000006669
 US/FDA report #
 FDA Use Only

A. Patient information

1. Patient identifier: ?-?
 2. Age at time of event: 35 yr
 or Date of birth: ??/??/??
 3. Sex: female male
 4. Weight: UNK lbs or UNK kgs

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 22/22/99 (month/day/yr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event: ??/??/99
 4. Date of this report: 08/22/00

5. Describe event or problem:
 Report published in 1999 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System (case 269) of a 35 year old (gender not stated) who intentionally misused acetaminophen/diphenhydramine, acetaminophen/oxycodone carisoprodol and died. No further information available at this time.

6. Relevant tests/laboratory data, including dates:
 Urine toxicology for phenothiazine and unspecified (Lab data cont.)
 (Cont.)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 Drug abuse, gastroparesis, G-tube insertion, several suicide attempts with multiple drugs

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 **TYLOX (capsule) (OXYCODONE/ACETAMINOPHEN)**
 #2 **SOMA (CARISOPRODOL)**

2. Dose, frequency & route used
 #1 oral
 #2 oral

3. Therapy dates (if unknown, give duration)
 #1 ??/??/??
 #2 ??/??/?? - ??/??/99

4. Diagnosis for use (indication)
 #1 PAIN
 #2 PAIN

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, #2
 7. Exp. date (if known): #1, #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)

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)
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)

2. Phone number: 908-704-4504

3. Report source (check all that apply):
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer: 08/14/00
 5. (A)NDA # 88-790
 IND #
 PLA #
 pre-1938 yes
 OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply):
 5-day 15-day
 10-day periodic
 Initial follow-up # 1

8. Adverse event term(s):
 1) DRUG ABUSE
 2) ACIDOSIS
 3) HYPOTENSION
 4) HEPATIC FAILURE

9. Mfr. report number: PRIUSA2000006669

E. Initial reporter

1. Name, address & phone #
 Dr. Toby Litovitz
 American Assoc of Poison Control Centers
 3201 New Mexico Avenue, Suite 310
 Washington, DC 20016
 USA
 Phone #: 202-362-7493

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 facility, distributor, manufacturer or product caused or contributed to the event.

1500A Facsimile

AUG 25 2000

AUG 28 2000

DSS

UD/Date report #
 PRIUSA2000006669
 UD/Date report #
 FDA Use Only

A. Patient information

1. Patient identifier _____ 2. Age at time of event: _____ or _____ Date of birth: _____ 3. Sex female male 4. Weight _____ lbs or _____ kgs

In confidence

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 (month/year) life-threatening hospitalization - initial or prolonged

disability congenital anomaly required intervention to prevent permanent impairment/damage other: _____

3. Date of event (month/year) _____ 4. Date of this report (month/year) _____

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #3 **PARALIN PM (TYLENOL PM)**
 #4 _____

2. Dose, frequency & route used
 #3 **2 tablets daily, oral**
 #4 _____

3. Therapy dates (if unknown, give duration)
months (or best estimate)
 #3 **??/??/?? - ??/??/??**
 #4 _____

4. Diagnosis for use (indication)
 #3 **PAIN**
 #4 _____

5. Event abated after use stopped or dose reduced
 #3 yes no doesn't apply
 #4 yes no doesn't apply

6. Lot # (if known) #3 _____ #4 _____

7. Exp. date (if known) #3 _____ #4 _____

8. Event reappeared after reintroduction
 #3 yes no doesn't apply
 #4 yes no doesn't apply

9. NDC # - for product problems only (if known)
 #3 _____ #4 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)

2. Phone number

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/year)

5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 yes OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day 10-day periodic Initial follow-up # _____

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name, address & phone #

2. Health professional? yes no

3. Occupation

4. Initial reporter also sent report to FDA yes no 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.

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AUG 28 2000



B. Adverse event or product problem

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

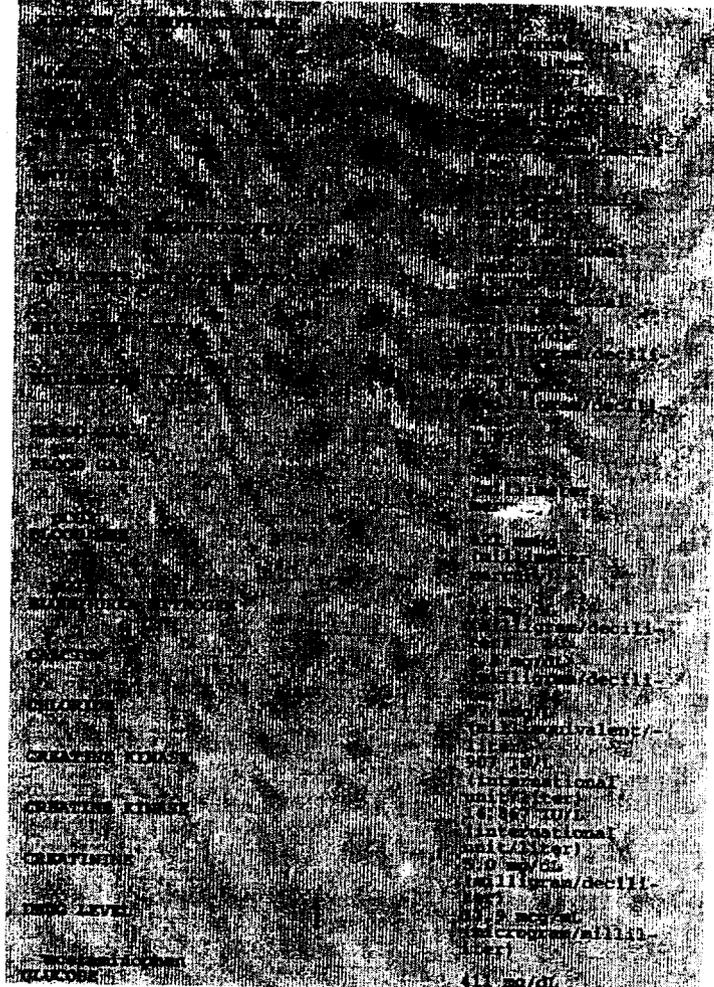
when he could not awaken her, he called 911. In the emergency department, she was intubated for airway protection and shock. Her blood pressure fell to 60 mmHg by palpitation. Norepinephrine was given and rapidly titrated to 25 mcg/minute. Several ampules of sodium bicarbonate were given for acidosis. Oral N-acetylcysteine (NAC) treatment was initiated. Abnormal labs were AST >7,500 U/L, ALT 5,775 U/L, total bilirubin 3.6 mg/dL, PTT 44.1 sec, INR 4.5, CK 907 U/L, WBC 33.9x10³ cells/mm³, glucose 411 mg/dL, pH 7.03, pCO₂ 20 mmHg, PO₂ 422 mmHg, and O₂ saturation 97%. Acetaminophen was 11.9 mcg/mL, and her urine toxicology screen was positive for THC, metoclopramide, acetaminophen, phenothiazine, and unspecified opiates. She was admitted to the intensive care unit. Swan-Ganz catheter data was consistent with mild hypovolemic and low SVR hypotension. Cardiac output was inappropriately low for her clinical condition. The patient was transferred to a tertiary hospital for liver transplant evaluation. Additional lab results were: AST 13,700 U/L, ALT 6,140 U/L, LDH >21,500 U/L, total bilirubin 2.7 mg/dL, INR >10.7, PTT >106 sec, NH₄ 509 mcg/dL, Na⁺ 159 mEq/L, K⁺ 7.2 mEq/L, Cl⁻ 97 mEq/L, Ca⁺⁺ 4.8 mEq/L, Mg⁺⁺ 3.7 mEq/L, PO₄⁻ 15.4 mg/dL, BUN 14 mg/dL, SCr 5.0 mg/dL, Hgb 5.7 g/dL, Hct 17.9%, platelets 110,000/mm³, amylase 382 U/L, CK 14,867 U/L, and fibrinogen 101 mg/dL. The patient was not a transplant candidate due to her psychiatric history. An attempt at "medical management" was made and the family requested the discontinuation of life support systems. She died from progressive acidosis and hypertension sixteen hours after transfer.

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

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
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1	??/??/??			
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R.W. JOHNSON PHARM. RES. INST. USA
DIV. OF ORTHO PHARMACEUTICAL CORP.
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Raritan NJ 08869
USA

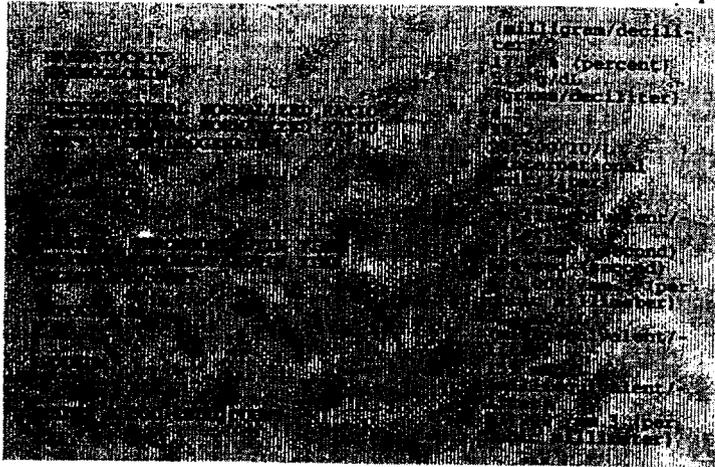


Continuation Sheet for FDA-3500A Form

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Mfr. report #: PRIUSA2000006669

Date of this report: 08/22/00



Source of report (Literature):

Seq No. : 1
Author : Toby Litovitz
Journal title : American Journal of Emergency Medicine
(pre-publication)
Year : 00
Article title : 1999 Annual Report of the American Association of
Poison Control Centers Toxic Exposure Surveillance
System

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AUG 28 2000

AUG 25 2000