Individual Safety Report

3409988-9-00-01

R.W. JOHNSON PHARM. RES. INST. USA

For use by user-facilities, ributors and manufacturers for **MANDATORY** reporting

Approved by FDA on 09/15/95

Mfr report # PRIUSA1999006538

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: ?-?
In confidence

2. Age at time of event: or 46 yr
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 ??/???/?? (mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other:

3. Date of event (mo/day/yr): ??/???/??

4. Date of this report (mo/day/yr): 11/16/99

5. Describe event or problem

Report published in 1991 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 226). A 46-year-old patient (sex unspecified) died following ingestion of acetaminophen, acetaminophen with hydrocodone, and acetaminophen with oxycodone. Intent of ingestion is unknown.

Additional information received 11-Nov-99: This 46 year old male, with a past medical history of an acetaminophen overdose two years prior to admission, ingested an unknown amount of acetaminophen with hydrocodone bitartrate, acetaminophen with oxycodone (identified on follow-up to be Percocet brand), and acetaminophen. It is not known if the ingestion was intentional. The family reported the patient to be confused and lethargic the day of admission. The patient was felt to be in septic shock with a temperature of 90 degrees F. Other vital sign information is unknown. On physical examination the patient was unresponsive on a ventilator, anuric with mydriasis and unequal pupils. The only available laboratory information available (Cont.)

6. Relevant tests/laboratory data, including dates

Laboratory information available: anion gap, 36 mEq/L, with liver and renal toxicity (laboratory tests unspecified and values not reported); blood alcohol level, 7 mg/dL; CPK, normal and a non-toxic serum acetaminophen level (laboratory values not reported)

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

Acetaminophen overdose two years prior to admission

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C. Suspect medication(s)

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

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

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

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

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 (& mfring 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 (mo/day/yr): 11/11/99

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) DEATH
2) SEPSIS
3) ANURIA
4) COMA
5) CONFUSION
6) SOMNOLENCE
7) MYDRIASIS

9. Mfr. report number: PRIUSA1999006538

F. Initial reporter

(Cont.)

1. Name, address & phone #
Dr. Toby Litovitz
National Capital Poison Center
Georgetown University Hospital
3800 Reservoir Road NW
Washington, DC 20007
USA

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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.

3500A Facsimile

R.W. JOHNSON PHARM. RES. INST. USA

Individual Safety Report

3409988-9-00-02

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999006538

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier — In confidence
2. Age at time of event: or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ____ lbs or ____ 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 (mm/dd/yr)
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mm/dd/yr)
4. Date of this report (mm/dd/yr)
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 TYLENOL (PARACETAMOL)
   #4
2. Dose, frequency & route used
   #3 oral
   #4
3. Therapy dates (from/to (or best estimate)) (if unknown, give duration)
   #3 ??/???/??
   #4
4. Diagnosis for use (indication)
   #3 UNKNOWN
   #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)
10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfring 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 (mm/dd/yr)
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

F. Initial reporter

1. Name, address & phone #

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2. Health professional? ☐ yes ☐ no
3. Occupation
4. Did you send 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.

3500A Facsimile

R.W. JOHNSON PHARM. RES. INST. USA
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Raritan NJ 08869
USA

Individual Safety Report
3409988-9-00-03

Continuation Sheet for FDA-3500A Form

Mfr. report # : PRIUSA1999006538

Date of this report : 11/16/99

B. Adverse event or product problem

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

was: anion gap, 36 mEq/L, with liver and renal toxicity; blood alcohol level, 7 mg/dL; CPK, normal; and a non-toxic serum acetaminophen level. This level apparently returned late and the patient was not treated with N-acetylcysteine. The patient expired seven hours after admission.

G. All manufacturers

8. Adverse event term(s)

8) HEPATIC FUNCTION ABNORMAL
9) RENAL FUNCTION ABNORMAL

Source of report (Literature):

Seq No.	:	1
Author	:	Toby Litovitz
Journal title	:	1991 Annual Report of the American Association of Poison Control Centers National Data Collection System
Year	:	92
Edition	:	10(5)
Page number	:	From 452 To 505
Article title	:	American Journal of Emergency Medicine

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