3418434-0-00-01

ES. INST. USA
user-facilities,
manufacturers for
ORY reporting

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999006644

UF/Dist report #

File Use Only

THE

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A. Patient information

1. Patient identifier: ?-? In confidence
2. Age at time of event: or 63 yr; Date of birth: ??/???/??
3. Sex: [x] female [ ] male
4. Weight: UNK lbs or UNK kgs

B. Adverse event or product problem

1. [x] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
   - [x] death ??/???/?? (mo/day/yr)
   - [ ] life-threatening
   - [x] 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): 12/02/99

5. Describe event or problem

Report published in 1994 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 249). A 63-year-old patient (sex unspecified) on treatment with acetaminophen, acetaminophen with oxycodone, and propoxyphene died following an unspecified therapy error. Patient experienced prehospital (cardiac and/or respiratory) arrest. Serum acetaminophen level 25 mcg/mL. Exposure to medication was chronic.

Report received 29-Nov-99: A 63-year-old woman who had been taking approximately 100 325mg acetaminophen tablets per three days, for a "long time" presented to the emergency department (ED) in cardiac arrest. She was resuscitated in the ED, intubated, and admitted to the intensive care unit (ICU). Serum acetaminophen level was 25 mcg/mL; acetylsalicylic level, [illegible] mg/dL; pH, 6.9; lactate [illegible] mmol/L; prothrombin time, 23 sec; [illegible] IU/L; [illegible] IU/L (question of lab error); total bilirubin, 3.0 mg/dL; creatinine, 1.2 mg/dL; and BUN, 40 mg/dL. She received aggressive supportive care in (Cont.)

6. Relevant tests/laboratory data, including dates

Additional information received 29-Nov-99: lab data updated. (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.)

unknown

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C. Suspect medication(s)

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

2. Dose, frequency & route used
   - #1 oral
   - #2 325 mg, 100 in 3 day(s), oral

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 ??/???/??
   - #2 ??/???/??

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

5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [ ] no [x] 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 [x] 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
   - [x] literature
   - [ ] consumer
   - [x] health professional
   - [ ] user facility
   - [ ] company representative
   - [ ] distributor
   - [ ] other:

4. Date received by manufacturer (mo/day/yr): 11/29/99

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 [x] 15-day
   - [ ] 10-day [ ] periodic
   - [ ] Initial [x] follow-up # 1

8. Adverse event term(s)
   1) CARDIAC ARREST
   2) SUDDEN DEATH

DEC 09 1999

9. Mfr. report number: PRIUSA1999006644

F. Initial reporter

1. Name, address & phone #

Dr. Toby Litovitz
National Capital Poison Center
Georgetown University Hospital
3800 Reservoir Road NW
Washington, DC 20007
USA

2. Health professional? [x] yes [ ] no
3. Occupation: Physician
4. Initial reporter also sent report to FDA [ ] yes [ ] no [x] 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

3418434-0-00-02

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...nd manufacturers for
...ATORY reporting

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999006644

UF/Dist report #

FDA Use Only

...age 2 of 3

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 ____ (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)

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.)

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ADVERSE EVENT

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #3 PROPOXYPHENE (DEXTROPROPOXYPHENE)
   #4

2. Dose, frequency & route used
   #3 oral
   #4

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #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 (mo/day/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

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F. 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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Mfr. report # : PRIUSA1999006644

Date of this report : 12/02/99

B. Adverse event or product problem

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

ICU and was treated with N-acetylcysteine, however, she died within 12 hours of admission.

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

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
1	??/???/??	ALT	5 IU/L (international unit/liter)	
		Question of lab error		
		AST	7,000 IU/L (international unit/liter)	
		BILIRUBIN	3.0 mg/dL (milligram/deciliter)	
		BLOOD UREA NITROGEN	40 mg/dL (milligram/deciliter)	
		CREATININE	3.2 mg/dL (milligram/deciliter)	
		DRUG LEVEL	25 mcg/mL (microgram/milliliter)	
		acetaminophen		
		DRUG LEVEL	4 mg/dL (milligram/deciliter)	
		acetylsalicylic acid		
		LACTATE	19 mmol/L (millimole/liter)	
		PH	6.9	
		PROTHROM TIME	23 sec (second)	

Source of report (Literature):

Seq No.	:	1
Author	:	Toby Litovitz
Journal title	:	1994 Annual Report of the American Association of Poison Control Centers National Data Collection System
Year	:	95
Edition	:	13(5)
Page number	:	From 551 To 597
Article title	:	American Journal of Emergency Medicine

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