Individual Safety Report

3396829-1-00-01

MED

FDA MEDICAL PRODUCTS REPORTING

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

For use by user-facilities, ers for reporting

2

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999006500

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: ?-?
In confidence

2. Age at time of event: 77 yr
or 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 ??/???/?? (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): 11/04/99

5. Describe event or problem

Report published in 1988 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 163). A 77-year-old patient (sex unspecified) died following accidental misuse of acetaminophen with codeine, and acetylsalicylic acid. Serum acetaminophen level 50.6 mcg/mL.

Additional information received 4-Nov-99: This 77 year old female with a history of alcohol abuse and known cirrhosis was found obtunded at home after ingesting an unknown number of acetaminophen with codeine 30 mg the previous night. On arrival to the emergency room, the patient received 50% dextrose and naloxone without improvement. Vitals were heart rate, 88; BP, 90/60 mmHg; respiratory rate, 24; and temperature, 34.6 degrees C. ABG's were pH, 7.36; PCO2, 29 mmHg; and PO2,80 mmHg. Other labs on admission include sodium, 127 mEq/L; potassium, 4.6 mEq/L; chloride, 97 mEq/L; bicarbonate, 18 mmHg; BUN, 47 mg/dL; and glucose, 49 mg/dL, AST, 4270 U/L; prothrombin time, 29.4 seconds (control 11.8 seconds), total bilirubin, 0.6 mg/dL; and (Cont.)

6. Relevant tests/laboratory data, including dates

Acetaminophen levels were 50.6 mcg/ml at 4:00 am (on admission), 49.0 mcg/mL at 8:30 am, and 41 mcg/mL at 12 noon. (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.)

Alcohol abuse, cirrhosis

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TYLENOL W/CODEINE NO. 3(tablet)(ACETAMINOPHEN/CODEINE)
#2 ASPIRIN(ACETYLSALICYLIC ACID)

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

3. Therapy dates (from/to (or best estimate)) (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 [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 (mm/dd/yr): 11/04/99

5. (A)NDA # 85-055
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) THERAPEUTIC RESPONSE INCREASED
2) HEPATIC FUNCTION ABNORMAL
3) PROTHROMBIN DECREASED
4) STUPOR

9. Mfr. report number
PRIUSA1999006500

E. Initial reporter

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

RECEIVED NOV 12 1999 BY:

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.
DIV.
920 U
P.O. Box
Raritan N
USA

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ntinuation Sheet for FDA-3500A Form

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Date of this report : 11/04/99

B. Adverse event or product problem

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

acetylsalicylic acid 35 mg/L. Acetaminophen levels were 50.6 mcg/ml at 4:00 am (on admission), 49.0 mcg/mL at 8:30 am, and 41 mcg/mL at 12 noon. Acetylcysteine was given upon admission to the intensive care unit. The patient became progressively obtunded and expired 20 hours after admission to the hospital. No autopsy was performed.

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

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
1	??/???/??	ASPARTATE AMINOTRANSFERASE	4270 IU/L (international unit/liter)	
		BICARBONATE	18 mmHg (millimeter mercury)	
		BILIRUBIN, TOTAL	0.6 mg/dL (milligram/deciliter)	
		BLOOD GAS PCO2	29 mmHg (millimeter mercury)	
		BLOOD GAS PO2	80 mmHg (millimeter mercury)	
		BLOOD UREA NITROGEN	47 mg/dL (milligram/deciliter)	
		CHLORIDE	97 mEq/L (milliequivalent/liter)	
		DRUG LEVEL acetaminophen	50.6 mcg/mL (microgram/milliliter)	
		DRUG LEVEL	35 mg/L (milligram/liter)	
		GLUCOSE	49 mg/dL (milligram/deciliter)	
		PH	7.36	
		POTASSIUM	4.6 mEq/L (milliequivalent/liter)	
		PROTHROM TIME (control 11.8 seconds)	29.4 sec (second)	
		SODIUM	127 mEq/L (milliequivalent/liter)	

Source of report (Literature):

Seq No.	:	1
Author	:	Toby Litovitz
Journal title	:	1988 Annual Report of the American Association of Poison Control Centers National Data Collection System
Year	:	89
Edition	:	7(5)
Page number	:	From 495 To 545
Article title	:	American Journal of Emergency Medicine

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