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R. W. JOHNSON PHARM. RES. INST. USA  
Ser. facilities,  
Manufacturers for  
RY reporting

Approved by FDA on 09/15/95

Mfr report #	PRIUSA1999006531
UFDat report #	
FDA Use Only	

DA MEDICAL PRODUCTS REPORTING

of 2

**A. Patient information**

1. Patient identifier ?--?	2. Age at time of event: 41 yr Date of birth: ??/??/??	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs UNK kg
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**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 22/222/22 (m/d/yyyy)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (m/d/yyyy) ??/??/??

4. Date of this report (m/d/yyyy) 11/12/99

5. Describe event or problem

Report published in 1991 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 253). A 41-year-old patient (sex unspecified) died following intentional misuse of acetaminophen with codeine, and ethanol. Serum acetaminophen level 14 mcg/mL. Exposure to medication was chronic.

Additional information received 11-Nov-99: This 41 year old female with chronic alcoholism was found on the street complaining of abdominal pain and dizziness. Initial blood pressure was 40 mmHg systolic, and with normal saline her blood pressure increased to 90 mmHg. On arrival, in the emergency Department, the patient denied melena or hematemesis. She gives additional history that she was taking "large amounts" of acetaminophen for a first and second degree burn of the hand. Physical examination: alert, cachectic. Vital signs: BP, 90 mmHg; heart rate, 120 beats/minute; and afebrile. Abdominal exam: decreased bowel sounds; enlarged liver was palpated; large amount of ascites; and no rebound. Rectal exam: guaiac was positive. Labs: WBC, (Cont.)

6. Relevant tests/laboratory data, including dates

Rectal exam: guaiac was positive, esophagogastroduodenoscopy: showed a large amount of blood (Lab data cont.)

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

Chronic alcoholism, first and second degree burn of the hand

**DSS**  
NOV 29 1999  
ADVERSE EVENT REPORTING SYSTEM

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labels, if known)  
 #1 **TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN-**  
 #2 **ETHANOL (ETHANOL)** (Cont.)

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

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

4. Diagnosis for use (indication)  
 #1 PAIN  
 #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 (m/d/yyyy)  
 11/11/99

5. (ANDA # 85-055)  
 IND # \_\_\_\_\_  
 PLA # \_\_\_\_\_  
 pre-1938  yes  
 OTC product  yes

6. If IND, protocol #

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

8. Adverse event term(s)  
 1) GI HAEMORRHAGE  
 2) COAGULATION DISORDER  
 3) HYPOTENSION  
 4) ASCITES  
 5) HEPATOMEALY  
 6) CACHEXIA  
 7) LAB VALUES ABNORMAL (Cont.)

9. Mfr. report number  
 PRIUSA1999006531

**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

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.

DA 01  
923 U.S. 1  
P.O. Box  
Raritan N.  
USA



**B. Adverse event or product problem**

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

3,000 U/L; Hct, 27%; Platelets, 101,000 U/L; Na, 126 mEq/L; K, 5.6 mEq/L; Cl, 93 mEq/L; bicarbonate, 10 mEq/L; Glucose, 202 mEq/L; BUN, 17 mg/dL; Creatinine, 2.8 mg/dL; prothrombin time, 35/13 seconds; partial thromboplastin time, 61/39 seconds; and acetaminophen level, 14 mcg/mL. Hospital course: esophagogastroduodenoscopy showed a large amount of blood but they were not able to localize a site of bleeding. The patient continued to be hypotensive and coagulopathic even after receiving large amounts of fresh frozen plasma and packed red blood cells. The patient expired 24 hours after arrival. N-acetylcysteine was started but was not completed secondary to the patient's unstable condition.

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

**Lab Result :**

Sl.No.	Test date	Test name	Test result	Normal value
1	??/??/??	BICARBONATE	10 mEq/L (milliequivalent/- liter)	
		BLOOD UREA NITROGEN	17 mg/dL (milligram/decili- ter)	
		CHLORIDE	93 mEq/L (milliequivalent/- liter)	
		CREATININE	2.8 mg/dL (milligram/decili- ter)	
		DRUG LEVEL	14 mcg/mL (microgram/millil- iter)	
		acetaminophen		
		GLUCOSE	202 mEq/L (milliequivalent/- liter)	
		HAEMATOCRIT	27 % (percent)	
		PARTIAL THROMBOPLASTIN TIME	61 sec (second)	
		PLATELET COUNT	101,000 IU/L (international unit/liter)	
		POTASSIUM	5.6 mEq/L (milliequivalent/- liter)	
		PROTHROM TIME	35 sec (second)	
		SODIUM	126 mEq/L (milliequivalent/- liter)	
		WHITE BLOOD CELL/COUNT	3,000 IU/L (international unit/liter)	

**C. Suspect medication (Cont...)**

Seq No. : 1  
C.1 Suspect medication : TYLENOL WITH CODEINE (unspecified) (ACETAMINOPHEN/CODEINE)

**G. All manufacturers**

**8. Adverse event term(s)**

- 8) ABDOMINAL PAIN
- 9) DIZZINESS
- 10) DRUG ABUSE

**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  
: 92  
: 10(5)  
: From 452 To 505  
Article title : American Journal of Emergency Medicine

**DSS**

NOV 29 1999

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NOV 24 1999