



HARM. RES. INST. USA
For use by user-facilities,
tributors and manufacturers for
MANDATORY reporting

Approved by FDA on 08/15/95

Mfr report # PRIUSA1999006730
UFDist report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information			
1. Patient identifier ? - ?	2. Age at time of event: 35 yr	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs UNK kg
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death 22/2222/??		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other:			
3. Date of event ??/??/??	4. Date of this report 12/02/99		
5. Describe event or problem			
<p>Report published in 1996 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 203). A 35-year-old patient (sex unspecified) on treatment with acetaminophen, and acetaminophen with codeine died following an unspecified therapy error. Serum acetaminophen level 83 mcg/mL. Exposure to medication was chronic.</p> <p>Additional information received on 29-NOV-99: A 35-year-old man with a history of alcohol abuse and pancreatitis had been taking acetaminophen and acetaminophen with codeine (#3) over a few days for abdominal pain. He was admitted to the hospital for confusion and developed gastrointestinal bleeding, encephalopathy and hepatic and renal failure. He presented with an acetaminophen level of 83 mcg/mL, SGPT of 7,000 IU/L and a bilirubin of 5.2 mg/dL. His coagulopathy and gastrointestinal bleeding progressed with a falling blood pressure and hematocrit that initially responded to treatment with 7 litres of intravenous fluid, 6 units packed RBC's and 4 units fresh frozen plasma. However, he continued</p>			
6. Relevant test/laboratory data, including dates (Lab data cont.)			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Additional information received on 29-NOV-99: History of alcohol abuse and pancreatitis			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 TYLENOL W/CODEINE NO. 3 (tablet) (ACETAMINOPHEN/CODEINE)			
#2 ACETAMINOPHEN (PARACETAMOL)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration)	
#1 oral		#1 ??/??/??	
#2 oral		#2 ??/??/??	
4. Diagnosis for use (indication)		5. Event abated after use stepped or dose reduced	
#1 UNKNOWN		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 UNKNOWN		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
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)		2. Phone number
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)		908-704-4504
3. Report source (check all that apply)		
<input type="checkbox"/> foreign		
<input type="checkbox"/> study		
<input checked="" type="checkbox"/> literature		
<input type="checkbox"/> consumer		
<input checked="" type="checkbox"/> health professional		
<input type="checkbox"/> user facility		
<input type="checkbox"/> company representative		
<input type="checkbox"/> distributor		
<input type="checkbox"/> other:		
4. Date received by manufacturer (m/d/yyyy)	5. (A)NDA #	
11/29/99	85-055	
6. If IND, protocol #	IND #	
	PLA #	
7. Type of report (check all that apply)	pre-1938	<input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product	<input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	8. Adverse event term(s)	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1	1) DEATH	
	2) GI HAEMORRHAGE	
	3) ENCEPHALOPATHY	
	4) HEPATIC FAILURE	
	5) RENAL FUNCTION ABNORMAL	
	6) HYPOTENSION	
	7) COAGULATION DISORDER	
9. Mfr. report number		
PRIUSA1999006730		

I. 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?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

ADVERSE EVENT REPORTING
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

DEC 15 1999

DEC 14 1999



3421496-8-00-02

B. Adverse event or product problem

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

to be unstable and was intubated. Intravenous N-acetylcysteine was also administered. The patient expired 2 days after admission.

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

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
1	??/??/??	DRUG LEVEL acetaminophen	83 mcg/mL (microgram/milliliter)	

Source of report (Literature):

Seq No. : 1
 Author : Toby Litovitz
 Journal title : 1996 Annual Report of the American Association of
 Poison Control Centers National Data Collection
 System
 Year : 97
 Edition : 15(5)
 Page number : From 447 To 500
 Article title : American Journal of Emergency Medicine

DSS

DEC 15 1999

OVERSIGHT

DEC 14 1999