

Individual Safety Report



3417738-5-88-01

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

Approved by FDA on 09/25/95

Mfr report # PRIUSA1999006679
UP/Date report #
FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information			
1. Patient identifier ? - ?	2. Age at time of event 40 yr Date of birth: ??/??/??	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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 ??/??/?? (m/d/y) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:			
3. Date of event (m/d/y) ??/??/??	4. Date of this report (m/d/y) 12/06/99		
5. Describe event or problem Report published in 1995 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 231). A 40-year-old patient (sex unspecified) died following the ingestion of acetaminophen with oxycodone. Intent of ingestion is unknown. Serum acetaminophen level 37 mcg/mL. Exposure to medication was chronic. Additional information received 25-Nov-99. A 40-year-old male patient with a history of chronic alcohol abuse presented to an emergency department with a history of chronically ingesting acetaminophen/oxycodone (500mg/5mg) for pain relief. There was no history of alcohol abuse. The patient presented with pain, nausea, vomiting, and abdominal pain. Laboratory tests showed elevated liver enzymes and a total bilirubin of 1.2 mg/dL. The patient received supportive care and was discharged on oral pain medication.			
6. Relevant test/laboratory data, including dates (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.) Additional information received 25-Nov-99: hepatomegaly.			

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C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known) #1 TYLOX (capsule) (OXYCODONE/ACETAMINOPHEN)			
2. Dose, frequency & route used #1 unk, 4 in 1 day(s), oral		3. Therapy dates (if unknown, give duration) (from/to or best estimate) #1 ??/??/??	
4. Diagnosis for use (indication) #1 UNKNOWN		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known) #1		7. Exp. date (if known) #1	
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		9. NDC # - for product problems only (if known) #2	
10. Concomitant medical products and therapy dates (exclude treatment of event) No Concomitant Products Reported			
D. All manufacturers			
1. Contact office - name/address (& mailing 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	
4. Date received by manufacturer (m/d/y) 11/25/99		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:	
6. If IND, protocol #		7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial	
9. Mfr. report number PRIUSA1999006679		8. Adverse event term(s) LIVER FUNCTION ABNORMAL, BILIRUBIN DECREASED, HEPATOMEGALY, GASTROENTERITIS (Cont.)	
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? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Physician	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 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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B. Adverse event or product problem

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

was difficult to obtain but approximately 24 hours after presentation the patient died. Laboratory values revealed that the patient was acidotic with a serum bicarbonate of .15 mEq/L; had renal insufficiency with a blood urea nitrogen of 12 mg/dL and a serum creatinine of 2.2 mg/dL; and had a coagulopathy with a prothrombin time of 22.8 seconds and an international normalized ratio of 2.23. Liver function tests at the time of death were not available.

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	36.8 mcg/mL (microgram/milliliter)	

G. All manufacturers

8. Adverse event term(s)

7) AGITATION

Source of report (Literature):

Seq No. : 1
 Author : Toby Litovitz
 Journal title : 1995 Annual Report of the American Association of
 Poison Control Centers National Data Collection
 System
 Year : 96
 Edition : 14 (5)
 Page number : From 487 To 537
 Article title : American Journal of Emergency Medicine

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ADVERSE EVENT