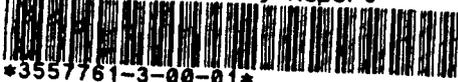


Individual Safety Report



UM. RES. INST. USA  
 for use by user-facilities,  
 users and manufacturers for  
 Mandatory reporting

Approved by FDA on 09/15/95

Mfr. report # <b>PRIUSA2000006672</b>
U7/Date report #
FDA Use Only

FD FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information			
1. Patient identifier ? - ?	2. Age at time of event: 43 yr or Date of birth: ??/??/??	3. Sex <input checked="" type="checkbox"/> female <input 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 ??/??/99 (m/d/yy)		<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 (m/d/yy) ??/??/99	4. Date of this report (m/d/yy) 08/17/00		
5. Describe event or problem			
<p>Report published in 1999 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System (case 309) of a 43 year old (gender not specified) who intentionally misused acetaminophen/oxycodone and died. No further information available at this time.</p> <p><b>Additional information received 14-Aug-00:</b> A 43-year-old woman was transported to the hospital with acute status changes. She was found to be unresponsive with hepatic and renal failure. History from family later revealed that the patient was taking Percocet (acetaminophen/oxycodone) (not TYLOX as previously reported) although dose and duration of therapy were not known. Admission laboratory tests showed: acetaminophen 20 mcg/mL, AST/ALT "1,000s" U/L, BUN 2.0 mg/dL, Cr 2.6 mg/dL, potassium 6.1 mcg/L, PT 55.9 seconds, PTT 38 seconds, and ammonia 187 mcg/dL. She received a loading dose of N-acetylcysteine orally and was started on dopamine and norepinephrine infusions for hypotension. She was not considered a good candidate for liver transplant because of a history of drug abuse.</p> <p>(Cont.)</p>			
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.)			
<p>Drug abuse unknown</p> <p style="text-align: center;"><b>DSS</b> <b>AUG 25 2000</b></p>			

C. Suspect medication(s)	
1. Name (give labeled strength & mfr/labeler, if known)	
#1 TYLOX (capsule) (OXYCODONE/ACETAMINOPHEN)	
#2 _____	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 oral	#1 ??/??/?? - ??/??/99
#2 _____	#2 _____
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 UNKNOWN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 _____	#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 _____
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
#1 _____	
#2 _____	
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)	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
4. Date received by manufacturer (m/d/yy) 08/14/00	3. Report source (check all that apply)
6. If IND, protocol #	<input type="checkbox"/> foreign
7. Type of report (check all that apply)	<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	<input checked="" type="checkbox"/> literature
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	<input type="checkbox"/> consumer
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1	<input checked="" type="checkbox"/> health professional
9. Mfr. report number PRIUSA2000006672	<input type="checkbox"/> user facility
	<input type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other:
	8. Adverse event term(s)
	1) DRUG ABUSE
	2) HYPOTENSION
	3) HEPATIC FAILURE
	4) RENAL FAILURE ACUTE

F. Initial reporter			
1. Name, address & phone #			
Dr. Toby Litovitz American Assoc of Poison Control Centers 3201 New Mexico Avenue, Suite 310 Washington, DC 20016 USA Phone #: 202-362-7493			
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	

3500A Facsimile

**AUG 24 2000**

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report



\*3557761-3-00-02\*

Continuation Sheet for FDA-3500A Form

Page 2 of 2

Mfr. report #: PRIUSA2000006672

Date of this report: 08/17/00

B. Adverse event or product problem

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

abuse and expired on the second hospital day.

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

Lab Result:

Sl.No.	Test date	Test name	Test result	Normal value
1	??/??/??	ALANINE AMINOTRANSFERASE	1,000 IU/L (international unit/liter)	
		ASPARTATE AMINOTRANSFERASE	147 mcg/dL (microgram/decililiter)	
		BLOOD UREA NITROGEN	1,000 IU/L (international unit/liter)	
		CREATININE	6 mg/L (milligram/liter)	
		GLUCOSE	2.8 mg/dL (milligram/decililiter)	
		HEMOGLOBIN	20 mcg/mL (microgram/milliliter)	
		PROTHROMBIN TIME	18 sec (second)	
		PT/APTT	18 sec (second)	

Source of report (Literature):

Seq No. : 1  
 Author : Toby Litovitz  
 Journal title : American Journal of Emergency Medicine (pre-publication)  
 Year : 00  
 Article title : 1999 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System

DSS

AUG 25 2000

AUG 24 2000