

Individual Safety Report



\*3396847-3-00-01\*

U.S. RES. INST. USA  
or use by user-facilities,  
distributors and manufacturers for  
MANDATORY reporting

Approved by FDA on 09/29/98

Mfr report #	PRIUSA1999006513
USFDI report #	
FDA Use Only	

Page 1 of 3

A. Patient Information			
1. Patient Identifier ? - ?	2. Age at time of event: 61 yr Date of birth: ??/??/??	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs UNK kg
B. Adverse event / product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Cause(s) attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death 22/222/22 (month/year)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____			
3. Date of event (month/year)	??/??/??	4. Date of this report (month/year)	11/08/99
5. Describe event or problem			
<p>Report published in 1989 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 211). A 61-year-old patient (sex unspecified) died following ingestion of acetaminophen with chlorzoxazone. Intent of ingestion is unknown.</p> <p>Additional information received 04-Nov-99: A 61-year-old female was found unresponsive and brought to the emergency department after the ingestion of chlorzoxazone, acetaminophen and ketoprofen. She was lavaged in the emergency department with pill fragments noticed. The patient was intubated and admitted to the intensive care unit (ICU). Activated charcoal was given and it was felt that she had an aspiration. Antibiotics were started for the presumed aspiration pneumonia. Initial liver function tests were AST, 15,000; ALT, 5,000; and LDH, 18,500. An acetaminophen level drawn 12-24 hours after ingestion was undetectable. A prothrombin time the following day was noted to be 24 seconds and the partial thromboplastin time was 53. The patient remained in the ICU dependent on the (Cont.)</p>			
6. Relevant tests/laboratory data, including dates			
(Lab data cont.)			
(Cont.)			
7. Other relevant history, including preexisting medical conditions (pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (e.g., allergies, race, etc.)			
unknown			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 PARAFON FORTE DSC (500 mg caplet) (CHLORZOXAZONE)			
#2 ACETAMINOPHEN (PARACETAMOL)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) (month/year)	
#1 oral		#1 ??/??/??	
#2 oral		#2 ??/??/??	
4. Diagnosis for use (indication)		5. Event abated after use: stopped or discontinued	
#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			
D. 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	
4. Date received by manufacturer (month/year)		5. (ANDA # 11-529)	
11/04/99		IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC <input type="checkbox"/> yes product	
6. If IND, protocol #		8. Adverse event term(s)	
		1) DEATH 2) PNEUMONITIS 3) HEPATIC ENZYMES INCREASED 4) HYPOTENSION 5) OLIGURIA 6) DYSKINESIA (Cont.)	
7. Type of report (check all that apply)		9. Mfr. report number	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1		PRIUSA1999006513	
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?		3. Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		Physician	
4. Initial reporter class (same as 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.

NOV 12 1999

Individual Safety Report

R W JOHNSON DERM. RES. INST. USA  
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MANDATORY reporting



\*3398847-3-00-02\*

Approved by FDA on 09/28/93

Mfr. report #	PRIUSA1999006513
USFDA report #	
FDA Use Only	

**A. Patient information**

1. Patient identifier In confidence	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kg
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**B. Adverse event or product problem**

1. <input 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 type="checkbox"/> death (multiply)	<input type="checkbox"/> flexibility
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____
3. Date of event (multiply)	4. Date of this report (multiply)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known) #3 KETOPROFEN (KETOPROFEN) #4 _____		3. Therapy dates (if unknown, give duration, months (or best estimate)) #3 ???/??/?/?? #4 _____	
2. Dose, frequency & route used #3 oral #4 _____		5. Event abated after use stopped or dose reduced #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication) #3 UNKNOWN #4 _____		8. Event reappeared after reintroduction #3 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known) #3 _____ #4 _____	7. Exp. date (if known) #3 _____ #4 _____	9. NDC # - for product problems only (if known) #3 _____ #4 _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)			

**C. All manufacturers**

1. Contact office - name/address (& mailing site for devices)		2. Phone number
4. Date received by manufacturer (multiply)		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input 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 type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		
5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes		8. Adverse event term(s)
9. Mfr. report number		

**F. Initial reporter**

1. Name, address & phone #		
<div style="border: 2px solid black; padding: 5px; display: inline-block;"> <p>RECEIVED</p> <p>NOV 12 1993</p> <p>BY: _____</p> </div>		
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input 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.



\*3386847-3-00-03\*

Attachment Sheet for FDA-3500A Form

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Mfr. report #: PRIUSA1999006513

Date of this report: 11/08/99

**B. Adverse event or product problem**

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

ventilator. She occasionally moved extremities; however, they were not purposeful movements. On the 9th hospital day, the patient became hypotensive and her urinary output decreased. The patient expired on the 12th 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 ASPARTATE AMINOTRANSFERASE LACTIC DEHYDROGENASE PARTIAL THROMBOPLASTIN TIME PROTHROM TIME	5,000 U (unit) 15,000 U (unit) 18,500 53 sec (second) 24 sec (second)	

**G. All manufacturers**

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

**7) RESPIRATORY INSUFFICIENCY**

**Source of report (Literature):**

Seq No. : 1  
 Author : Toby Litovitz  
 Journal title : 1989 Annual Report of the American Association of  
 Poison Control Centers National Data Collection  
 System  
 : 90  
 : 8(5)  
 Page number : From 394 To 442  
 Article title : American Journal of Emergency Medicine

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 NOV 12 1999  
 BY: