

INDIVIDUAL Safety Report



For use by user facilities,
and manufacturers for
Mandatory reporting

Approved by FDA on 08/26/98

Mfr report #	PRIUSA1999000391
UF/Dist report #	
FDA Use Only	

Patient information

1. Patient identifier ? - ?	2. Age at time of event or 45 yr	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or 75 ____ 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 type="checkbox"/> death	<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: _____	<input type="checkbox"/> other: _____
3. Date of event (month/year) ??/??/??	4. Date of this report (month/year) 04/14/99

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997; 337:1112-7). Information provided based on extracted data from medical records of patients hospitalization for acetaminophen ingestion between 01-Jan-92 and 30-Apr-95. According to extracted data, a 45-year-old female with acute myelogenous leukemia (AML) and (+) hepatitis C virus was admitted for acute liver failure, cough and fever. Records did not indicate acetaminophen use prior to admission.

Detailed information received 29-Mar-99. Medical records indicate the patient with AML who had received 3rd cycle of chemotherapy on 03-Feb-95, was admitted to the hospital with productive cough, chest pain, febrile and pancytopenia. While hospitalized the patient received acetaminophen with codeine #3 1-2 tablets every 4-6 hours from 14-Feb-95 to 17-Feb-95 and acetaminophen regular strength 1-2 tablets on 15-Feb-95 and 16-Feb-95 for pain. On 18-Feb-95 the patient was transferred to the critical care unit for worsened signs (Cont.)

6. Relevant tests/laboratory data, including dates

16-Feb-95 chest x-ray: right lower lobe infiltrate
17-Feb-95 blood culture no fungus
18-Feb-95 acetaminophen level 5
20-Feb-95 right lower lobe, bilateral: no aspirated foreign bodies or fungus isolated, no pneumocystis seen
22-Feb-95 (+) test for hepatitis C virus antibody, immunoglobulin M pending (Cont.)

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

Drug abuse (presc. and otc medicine), Alcohol use, Contraceptives
AML M2 diagnosed Aug-94, intravenous drug abuse not in 4 years, HIV (-), hepatitis (-), tobacco 1-2 packs/day 10 years, alcohol none in 3 years

RECEIVED
APR 19 1999

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 TYLENOL W/CODEINE NO. 3 (tablet) (ACETAMINOPHEN/CODEINE)	
#2 TYLENOL (PARACETAMOL)	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 1 table, 4 hour(s), oral	#1 02/14/95 - 02/17/95
#2 1 table, day(s), oral	#2 02/15/95 - 02/16/95
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 PAIN	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 PAIN	#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)	
1) HIDAC (CYTARABINE) 7/7/7 (NORMENSAL) 02/14/95 - 02/03/95	
2) ORTHO NOVUM 7/7/7 (NORMENSAL)	

DSS

APR 20 1999

G. All manufacturers

1. Contact office - name/address	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) 03/29/99	3. Report source (check all that apply)
5. (A)NDA # 85-055	<input type="checkbox"/> foreign
6. If IND, protocol #	<input type="checkbox"/> study
7. Type of report (check all that apply)	<input type="checkbox"/> literature
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	<input type="checkbox"/> consumer
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	<input checked="" type="checkbox"/> health professional
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	<input type="checkbox"/> user facility
8. Adverse event term(s)	<input type="checkbox"/> company representative
1) HEPATIC FAILURE	<input type="checkbox"/> distributor
2) FEVER	<input type="checkbox"/> other: _____
3) PANCYTOPENIA	
4) COAGULATION DISORDER	
5) COUGHING	
6) CHEST PAIN	
7) ENCEPHALOPATHY	

I. Initial reporter

1. Name, address & phone #
DR. [REDACTED]
USA

II. Health professional?

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.



3242712-1-00-02

B. Adverse event or product problem

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

and symptoms, and concomitant acute liver failure. The patient had increased liver function tests, increased ammonia level with hepatic encephalopathy, coagulopathy and worsening renal function. Physicians attributed this to drugs (acetaminophen and possible others) and infectious etiology. Patient denied toxic ingestion or acetaminophen overdose. Acetaminophen with codeine #3 was discontinued and patient was treated with N-acetylcysteine. Patient was discharged with principle diagnosis of pneumonia. Records indicate patient expired on 17-Aug-96 of blast crisis or relapse of AML.

Note: This is a duplicate report of a case from McNeil Consumer Healthcare reference #0905688A.

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

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
1	02/03/95	ALANINE AMINOTRANSFERASE	29	
		ALBUMIN	3.4	
		ALKALINE PHOSPHATASE	100	
		ASPARTATE AMINOTRANSFERASE	31	
		BILIRUBIN, TOTAL	0.3	
		GAMMA GLUTAMYL TRANSFERASE	242	
		PROTHROM TIME	12	
		TOTAL PROTEIN	7.8	
		CREATININE	0.7	
		HAEMATOCRIT	29.2	
2	02/06/95	HAEMOGLOBIN	9.4	
		PLATELET COUNT	278	
		WHITE BLOOD CELL/COUNT	8	
		ALBUMIN	4.1	
		ALKALINE PHOSPHATASE	155	
	02/14/95	ASPARTATE AMINOTRANSFERASE	34	
		BILIRUBIN, TOTAL	0.6	
		HAEMATOCRIT	24.2	
		HAEMOGLOBIN	8.3	
		PLATELET COUNT	3	
4	02/17/95	TOTAL PROTEIN	8.3	
		WHITE BLOOD CELL/COUNT	0.5	
		ALANINE AMINOTRANSFERASE	3120	
		ALBUMIN	2.7	
		ALKALINE PHOSPHATASE	142	
		AMMONIA	110	
		ASPARTATE AMINOTRANSFERASE	9310	
		BILIRUBIN, TOTAL	5.2	
		CARBON DIOXIDE	19	
		CREATININE	1.7	
5	02/13/95	GAMMA GLUTAMYL TRANSFERASE	379	
		GLUCOSE	142	
		PLATELET COUNT	17	
		PROTHROM TIME	20.2	
		SODIUM	131	
		TOTAL PROTEIN	6.2	
		WHITE BLOOD CELL/COUNT	0.3	
		GLUCOSE	208	
		ALANINE AMINOTRANSFERASE	1429	
		ALBUMIN	2.5	
6	02/20/95	ALKALINE PHOSPHATASE	151	
		ASPARTATE AMINOTRANSFERASE	455	
		BILIRUBIN, TOTAL	4	
		BLOOD UREA NITROGEN	18	
		CARBON DIOXIDE	21	
		CHLORIDE	112	
		CREATININE	1	
		GAMMA GLUTAMYL TRANSFERASE	406	
		GLUCOSE	305	
		HAEMATOCRIT	20	
HAEMOGLOBIN	7			
PHOSPHORUS	2.3			
PLATELET COUNT	25			
PROTHROM TIME	16.8			
SODIUM	146			
WHITE BLOOD CELL/COUNT	2.4			

DSS

APR 20 1999

ADVERSE EVENT REPORTING SYSTEM

RECEIVED
APR 19 1999
BY:

9. Concomitant medical products

Seq No. : 1
 Concomitant Medical Product : HIDAC (CYTARABINE)
 Dose, frequency & route used : 1) unknow
 Diagnosis for use(indication) : 1) MYELOID LEUKEMIA, ACUTE



3242712-1-00-03

Continuation Sheet for FDA-3500A Form

Page 3 of 3

Mfr. report #: PRIUSA1999000391

Date of this report: 04/14/99

Seq No.
Concomitant Medical Product
Dose, frequency & route used

: 2
: ORTHO NOVUM 7/7/7 (NORMENSAL)
: 1) oral

G. All manufacturers

8. Adverse event term(s)

- 8) PNEUMONIA
- 9) RENAL FUNCTION ABNORMAL

DSS

APR 20 1999

ADVERSE EVENT REPORTING SYSTEM

RECEIVED
APR 19 1999
BY: