

Individual Safety Report

Knoll Pharmaceutical Company

Approved by FDA on 3/22/94



3315062-2-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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Mfr report #	USA010071
DP/Dist report #	
FDA Use Only	

Patient information			
1. Patient identifier ?? in confidence	2. Age at time of event: 38 yrs or Date of birth: UNK	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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 Unknown (m/d/yyyy)		<input type="checkbox"/> life-threatening	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> other:	
3. Date of event (m/d/yyyy)	UNK	4. Date of this report (m/d/yyyy)	07/21/99
5. Describe event or problem			
<p>Obtunded, elevated liver function test, liver failure, altered mental status</p> <p>The [redacted] Centers [redacted] reports a 38 year old female with a medical history of hepatitis C and intravenous drug use presented to the emergency department after having ingested several different acetaminophen containing products for one week for chronic back pain. She developed altered mental status and had elevated LFT. Acetaminophen level performed revealed 70.9 ug/ml. She rapidly became obtunded, requiring intubation and mechanical ventilation. Oral N-acetylcysteine was started. Her liver function deteriorated rapidly. The patient subsequently expired. *</p>			
6. Relevant tests/laboratory data, including dates			
APAP level (exact date unknown) 70.9 ug/mL			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>Hepatitis C, intravenous drug use</p> <p>Race: UNK</p> <p>Pregnant: UNK</p>			

C. Suspect medication(s)		
1. Name (give labeled strength & mfr/labeler, if known)		
#1	Hydrocodone acetaminophen	
#2	acetaminophen	
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1	UNK	#1 UNK to UNK Duration: 1 week
#2	UNK	#2 UNK to UNK Duration: 1 week
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced
#1	chronic back pain	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	chronic back 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)	8. Event reappeared after reintroduction
#1 UNK	#1 Unknown	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 UNK	#2 Unknown	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # - for product problems only (if known)		
#1 NI	#2 NI	
10. Concomitant medical products and therapy dates (exclude treatment of event)		
Name: None Dates:		

G. All manufacturers	
1. Contact office - name/address (& mfring site for devices)	2. Phone number
Knoll Pharmaceutical Company 3000 Continental Drive - North Mount Olive, New Jersey 07828-1224	(973) 426-2600
4. Date received by manufacturer	5. (A)NDA #
07/12/99	BB-058
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 <input type="checkbox"/> 10-day <input type="checkbox"/> periodic	OTC product <input type="checkbox"/> yes
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #	
9. Mfr. report number	3. Report source (check all that apply)
USA010071	<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.
	UNITED STATES
	8. Adverse event term(s)
	DEPRESSED LEVEL OF CONSCIOUSNESS, HEPATIC FUNCTION ABNORMAL NOS, HEPATIC FAILURE, MENTAL DULLNESS

E. Initial reporter			
1. Name, address & phone #			
[redacted] Centers [redacted] USA			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input type="checkbox"/> yes <input type="checkbox"/> no	UNKNOWN	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	

DSS
AUG 02 1999



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

* Item completed on continuation pages.

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3315062-2-00-02

MEDWATCH	A.1. Patient Identifier .. ??	G.9. Mfr. report number USA010071	Page 2 of 2
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B.5. Describe event or problem

[continuation:] No further information was available.

DSS
AUG 02 1999

RECEIVED
JUL 30 1999
By _____