

Individual Safety Report



3315067-1-00-01

Knoll Pharmaceutical Company

Mfr report # USA010114	Approved by FDA on 3/22/94
Dr/Inst report #	
	FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

Patient information

1. Patient Identifier .. ?? in confidence	2. Age at time of event: 46 yrs or Date of birth: UNK	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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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)	
death: Unknown (mortality) life-threatening 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/yyyy): UNK	4. Date of this report (m/d/yyyy): 07/22/99

5. Describe event or problem

Overdose, confusion, tachypnea, pneumonia, metabolic acidosis

The [redacted] Centers [redacted] reports a 46 year old male with a medical history of hemophilia and HIV had ingested 1 Vicodin tablet every hour to treat severe pain. He presented to the emergency department confused, tachypneic with metabolic acidosis (lactic acid=7, pH=7.2, pCO2=8-9). Pneumonia was confirmed by x-ray. An initial acetaminophen level 4 hours prior was 52 ug/mL. His AST/ALT was "normal or a little high" (exact values unspecified). Sodium bicarbonate was administered and the pH increased to 7.32. N-acetylcysteine (NAC) was initiated and a *

6. Relevant tests/laboratory data, including dates

Lactic acid=7, pH7.2, pCO2=8-9, x-ray positive pneumonia, initial acetaminophen level 52 ug/mL, AST/ALT "normal to a little high" (exact values unspecified), pH level = 7.32, 4 hour repeat acetaminophen level=46 ug/mL

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

Hemophilia and HIV
Race: UNK
Pregnant: NA

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 Hydrocodone acetaminophen		#1 UNK to UNK	
#2		#2	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 1 TAB Q1HR PO		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 severe pain		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input 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)	9. NDC # - for product problems only (if known)	
#1 UNK	#1 Unknown	#1 NI	#2
#2	#2	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 07828-1234		(973) 426-2600	
4. Date received by manufacturer 07/13/99		5. (A)NDA # 88-058 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
6. If IND, protocol #		3. Report source (check all that apply)	
7. Type of report (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:	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up#		UNITED STATES 8. Adverse event term(s) NON-ACCIDENTAL OVERDOSE, CONFUSION, TACHYPNOEA, PNEUMONIA NOS, METABOLIC ACIDOSIS	
9. Mfr. report number USA010114			

E. Initial reporter

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



FD-302a (Rev. 11-83)

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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3315067-1-00-02

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EDWATCH.	A.1. Patient Identifier .. ??	G.9. Mfr. report number USA010114	Page 2 of 2
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B.5. Describe event or problem

[continuation:] repeat 4-hour acetaminophen level was 46 ug/mL. The patient expired approximately 24 hours after admission. No further information was available.

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