



3456958-6-00-01

CRIBS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (First/Last)	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH			2a. AGE	3. SEX	4. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input checked="" type="checkbox"/> LIFE THREATENING
		Day	Month	Year	71 Yrs	F	Day	Month	Year	
		18	NOV	1928			15	DEC	1999	

7-13 DESCRIBE REACTION(S) (including relevant non-tab data)
 Clinical events: liver enzymes out of range (HEPATIC FUNCTION ABNORMAL NOS), atrial fibrillation (ATRIAL FIBRILLATION)
 Narrative: liver enzymes out of range, atrial fibrillation (PLC/0020)

 A 71 year-old female with a history of hypertension and coronary artery disease, was enrolled into the INVEST study, site #1168 (open label post-marketing). She initiated Isoptin SR 120 mg QD for hypertension on 02-Dec-99. On 15-Dec-99, the patient's blood was drawn and analyzed and was found to have an AST level in the 2,000 IU/L range resulting in hospitalization. Her prothrombin time and hematocrit were reportedly 8 sec. and 20 % respectively. Isoptin SR was discontinued. She developed atrial fibrillation "

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) ISOPTIN - SLOW RELEASE / VERAPAMIL HYDROCHLORIDE (batch #(s): UNK), PERCOCET (batch #(s): UNK), TYLENOL / PARACETAMOL (batch #(s): UNK)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) 120 MG, TAB, TAB	16. ROUTE(S) OF ADMINISTRATION PO, PO, PO	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
17. INDICATION(S) FOR USE hypertension, low back pain, low back pain		
18. THERAPY DATES (From/To) -	18. THERAPY DURATION NA, 1 year, NI	

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (include those used to treat reaction)
 Name: POTASSIUM (batch #: UNK), Dates: Unknown to Unknown, Dose: TAB Tablet, Route: By mouth, Indications: supplement
 Name: ASA / ACETYL SALICYLIC ACID (batch #: UNK), Dates: Unknown to Unknown, Dose: TAB Tablet, Route: By -

23. OTHER RELEVANT HISTORY (e.g. diagnosis, allergies, pregnancy with last month of period, etc.)
 Hypertension, coronary artery disease, on Percocet for low back pain due to osteoporosis
 Concomitant diseases(s): Hypercholesterolemia, low back pain

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Knoll Pharmaceutical Company 3000 Continental Drive - North Mount. Olive, New Jersey 07828-1234		<p style="font-size: 2em; font-weight: bold;">DSS</p> <p style="font-size: 1.5em; font-weight: bold;">FEB 14 2000</p>
	24b. MFR CONTROL NO. USA012050	
24c. DATE RECEIVED BY MANUFACTURER 20-DEC-1999	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT 19-JAN-2000	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP	

NI - No information available at this time UNK - Information unknown

* Item completed on continuation page(s)

JAN 27 2000

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CONTINUES PREVIOUS PAGE	1. PATIENT INITIALS (last, first)	24b. MFR CONTROL NO. USA012050
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7. 13 DESCRIBE REACTION(S) (including relevant treatment date)

(continuation:) on the night she was admitted to the ICU and has been given a total of 25 mg of atenolol IV drip. The patient was taking Percocet 6 tabs/ DAY concomitantly for low back pain for approximately one year. The event is ongoing. The investigator considers the event unlikely related to study medication.

Follow-up #1(27-Dec-99): The investigator reports that the liver enzyme elevation was due to liver toxicity caused by acetaminophen which was in the Percocet and in the Tylenol which the patient was taking for low back pain.

Follow-up #2(04-Jan-2000): The patient recovered with sequelae on 27-Dec-99 and was discharged from the hospital.

12. THERAPY DATES (name)(Suspect Drug)

2 DEC-99 to NA, ?? ???-98 to ??-DEC-99, Unknown to ??-DEC-99

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

(continuation:) Mouth, Indications: unknown

Name: ORGALON (batch #: UNK), Dates: Unknown to Unknown, Dose: CAP Capsule, Route: By mouth, Indications: unknown

Name: ALBUTEROL (batch #: UNK), Dates: Unknown to Unknown, Dose: PUFF Aerosol, Route: Inhalation, indications: unknown

Name: AEROBID / FLUMISOLIDE (batch #: UNK), Dates: Unknown to Unknown, Dose: PUFF Aerosol, Route: Inhalation, Indications: unknown

Name: VALIUM / DIAZEPAM (batch #: UNK), Dates: Unknown to Unknown, Dose: TAB Tablet, Route: By mouth, Indications: unknown

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