

RECEIVED AT DRUG SAFETY SURVEILLANCE

Individual Safety Report

3037690-4-00

27-FEB-1998-0444

A. Patient Information			
1. Patient Identifier in confidence	2. Age at time of event: 53 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 152 LB
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 checked="" type="checkbox"/> death 21/JUN/94 (mo/day/yr)		<input type="checkbox"/> disability	
<input checked="" 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:			
3. Date of event (mo/day/yr) 06/17/94	4. Date of this report (mo/day/yr) 02/11/98*		
5. Describe event or problem			
*4th f/u report: hepatocellular necrosis, encephalopathy, hepatic/renal fail, hepato-renal syndrome, metabolic acidosis, coagulopathy, tachycardia, positive stools, hypoglycemia, dehydration, hypothermia, hallucinations, jaundice, nausea, confusion, sleepiness w/BIAXIN. AMP for UTI 6/13/94-6/15. Cough, 103 F; CXR poss pulm infiltr. BIAXIN 6/15. Tired, sleepy, nausea 6/17; Tx w/PHENERGAN. Last APAP 4 g between 6-9 pm 6/18. Jaundice, halluc, confused 6/19. To ER: hypervent, acidotic, hypothermic. MD: septic shock w/multisystem fail. To ICU, Rx HCO3. ARF r/t dehydration, UTI w/enterococcus. Rx'd VANCOMYCIN, rehydrate. NG srage for pos BM. Asterixis, tachy; massive hepatocellular necrosis. Hep encephalopathy, renal fail poss r/t hepatorenal syndrome, hypoglycemia, acidosis, coagulopathy. CT: hepatomegaly, splenomegaly. Glucose, FFP Tx; intubated, sedated; transfer. Nonresponsive, scleral hematomas, fluid overload. Fulm liver fail 6/20. Inc BP support; pt anuric. Transplant deferred, poor risk. Liver Bx: hep artery ligation, portal caval shunt d/t BP. Died 6/21. No autopsy. Suspect drug-induced hep injury. Poss contributors: ETOH, APAP; poss viral, less likely autoimmune. Clinical presentation, liver path, labs consistent w/APAP hepatotoxicity. *Info differs from previous report.			
6. Relevant tests/laboratory data, including dates			
1994 Billi Ca/P AlkP SGOT/PT GGT LDE Uric Acid			
5/23 .9 /2.4	70	69/38	118 772
Liver path:			
6/19 8.1 8.6/11.3	315	18K/	14.3K 10.7 (adm)ACETAMINOPHEN
6/19 9.0	290	15.5K/4.5K	260 12.4K AMA:1:40 hepatotoxicity
WBC Plt BUN/Cr Gluc HB4 pH Na K/Cl PT/PTT			
5/23 6.5	190K	(10/93	SGOT 69, GGT 188) 6/19 40.1/50
6/19 11.2	25K	27/4.5,4	25 216 7.01 128,121 5.8/87 40.1/50
Hep A,B,C, EBV, CMV: neg; Liver Bx: subfulminant hepatitis			
6/19 1 pm ACETAMINOPHEN level: 12.5 ug/dL; AMA, ASMA, DC: neg			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
*HTN 1987. L breast benign tumor 1965, bursitis, HIV unk. No recent travel, hepatotoxin exp. IV drug use, blood Tx, liver d/o, hepatitis, or past macrolide use. NKA 5/94: macrocytosis, inc LFTs: nummular eczema, enterococcus Tx'd w/AMP x2 days. DECADRON, KWELL, BENADRYL Rx'd 5/20; DURICEF, SELDANE Rx'd 5/27. Baseline ec P. SGOT/SGPT ratios consistent w/ETOH abuse. Quit smoking 1988. Galactorrhea r/t PREMARIN; dose dec. PARLODEL Rx'd Since about 6/15. 6-8 TYLENOL QD. Race white.			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr./labeler, if known)			
#1 Abbott - Biaxin			
#2 Tylenol			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 500.000 MG PO BID		#1 06/15/94-06/18/94	
#2		#2 06/18/94	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Suspect Mycoplasma pneumonia		#1 <input type="checkbox"/> yes <input checked="" 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)	
#1 Unknown		#1 Unknown	
#2		#2	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply			
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Lotensin	Unknown-Unknown	20.0000	
Tylenol	Unknown-18JUN94		
Advil	Unknown-Unknown		
Premarin	Unknown-Unknown		
Provera	Unknown-Unknown		

G. All manufacturers(s)	
1. Contact office - name/address (& mfring site for devices)	
Jeanne Fox D-491 AP6B Abbott Laboratories 100 Abbott Park Road Abbott Park, Ill 60064-3500	
19Feb98 13:58:10	
2. Phone (847)937-5533	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input checked="" type="checkbox"/> health professional	
<input type="checkbox"/> user facility	
<input checked="" type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other	
12178E	
4. Date received by manufacturer (mo/day/yr) 02/11/98*	
5. (A)NDA # 50-662 IND # PLA # pre 1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
6. If IND, protocol #	
7. Type of report (check all that apply)	
<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 # 4	
8. Adverse event term(s) LIVER FAIL KIDNEY FAIL HEPATORENAL SYND SPLENOMEGALY ENCEPHALOPATHY	
9. Mfr report number 62673-FDA#12178E	

E. Initial reporter			
1. Name, address & phone #			
[Redacted] MD			
[Redacted] Street			
[Redacted]			
[Redacted]			
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			