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McNeil Consumer Healthcare
Ft. Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



Page ____ of ____

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In confidence	2. Age at time of event: 37 yrs Date of birth:	3. Sex () female (X) male	4. Weight lbs or 80 kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified acetaminophen 325 mg tablets #2 penicillin V 500mg (See Sect C10)			
B. Adverse event or product problem				2. Dose, frequency & route used #1 total of 10 tablets #2 500 mg, qid, po		3. Therapy dates (if unknown, give duration) from/to for best estimate #1 over 3 day period PTA #2 unknown dates; 4 days	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 crampy right upper quadrant pain #2 sore throat, headache, cough, fever		5. Event abated after use stopped or dose reduced #1 (X) Yes () No () N/A #2 (X) Yes () No () N/A	
2. Outcomes attributed to adverse event (check all that apply) () death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage (X) other: recovered				6. Lot # (if known) #1 unknown #2 unknown		7. Exp. date (if known) #1 unknown #2 unknown	
3. Date of event unknown (mo/day/yr)		4. Date of this report 10/27/99 (mo/day/yr)		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A			
5. Describe event or problem Lit report (Am J Gastroenterol 1999;94(1):236-240) of ASCITES & severe HEPATITIS complicating Epstein-Barr infection. According to report, a 37 yo male experienced sore throat, headache, cough & fever & was tx w/penicillin V for 4 days w/out improvement. Pt reevaluated 2 wks before admission & found to be monospot (+). Pt tx w/erythromycin for 10 days, which was completed 48 hrs prior to admission. Over a 3 day period prior to admission, pt developed anorexia, nausea & crampy RUQ pain for which he took a total of 10 APAP 325 mg tabs. Pt noticed onset of jaundice, tea colored urine (URINE ABNORMAL) & acholic stools 24-48h PTA. On admission, pt had FEVER & pharyngeal exudates, erythema, cervical LYMPHADENOPATHY & scleral icterus. Abdomen was mildly distended & moderately tender in RUQ. Pt was neurologically intact. BILIRUBIN, AST, ALT, WBC (LEUKOCYTOSIS), & PROTHROMBIN were INCREASED. Epstein-Barr antibody tests were (+). Other viral serologies & PCR were (-). Pt tx w/IV ZOSYN® & CIPRO®. APAP level was 10.13mg/mL. Pt required paracentesis (See Sect C10)				9. NDC # - for product problems only (if known)			
6. Relevant tests/laboratory data, including dates Initial exam: T=39.7, HR=89, RR=20, BP=168/62, Tbili=8.4, Dbili=6.2, Tprotein=6.9, albumin=3.5, alkphos=225, ALT=441, AST=4351, LDH=4081, WBC=5.8, Hgb=14.8, MCV=89.9, plt=146, glucose=90, Na=129, K=4.2, Cl=92, HCO3=27, Cr=0.8, BUN=9, amylase=39, (See Sect B7)				10. Concomitant medical products and therapy dates (exclude treatment of event) none (Sect B5 cont) of ascites. Pt tx w/4u FFP before paracentesis. Pt symptomatically improved and was d/c on day 9. Pt experienced a complete clinical & lab recovery over the next 6 mos. (Sect C1 cont) #3 erythromycin, 500 mg, qid, po			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic or renal dysfunction, etc.) no recent travel, mushroom or fish ingestion or herbal medicine use; denied tobacco use, IVDA, or tattoos; no ETOH use in previous 2 months; (Sect B6 cont) lipase=76; Day2:PT=24.5, ALT=5381, AST=6105; Day 4: albumin=1.9, TP=4.4; Day6: Tbili=18, Day 15: albumin=4.4, ALT=38, AST=28, LDH=404, EBV capsid IgG=1:40, EBV capsid IgM=1:40, EBV nuclear antigen=high, monospot (-)				G. All manufacturers			
				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303	
				4. Date received by manufacturer (mo/day/yr) 10/27/99		3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:	
				6. If IND, protocol #		(A) NDA # 19-872 IND # PLA # pre-1938 () Yes () No	
				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #		OTC product (X) Yes () No	
				9. Mfr. report number 1260933A		8. Adverse event term(s) ASCITES HEPATITIS URINE ABNORMAL FEVER LYMPHADENOPATHY BILIRUBINEMIA LEUKOCYTOSIS PROTHROMBIN INC	
				E. Initial reporter			
				1. Name, address & phone # [Redacted] MD [Redacted] Medical Center [Redacted] Drive [Redacted]		NOV 8 1993	
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			



Facsimile Form 3500A

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