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McNEIL CONS  
FORT W

Pa

Individual Safety Report



\*3037709-0-00\*

in 11/18/93

2A use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier  Case # 5 In confidence	2. Age at time of event: 48 yrs or Date of birth:	3. Sex ( ) female (X) male	4. Weight lbs or 74 kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 "about 2 gm", po #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 date unknown; "over 1 day" #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 flu-like symptoms #2		5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
2. Outcomes attributed to adverse event (check all that apply) ( ) death (mortality) ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
3. Date of event (m/d/y) 10/15/93		4. Date of this report (m/d/y) 02/11/98		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
5. Describe event or problem  Reports of 19 cases compiled by attorney & sent to FDA; Agency forwarded these reports to McNeil upon request to Docket No. 77N-094W, Ref. 94, Vol. 6 of 7. Of the 19 cases, 11 were previously submitted to FDA by McNeil (Mfr# 0158783A, 0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A, 0673820A). Case #5 indicates 48(47)yo M (took 2g TYLENOL over 1 day. Pt had been consuming EtOH quite heavily & on 10/15/93 taken to ER w/HEMATEMESIS (vomiting bright red blood/clot). PE revealed swollen face (FACE EDEMA) & CONVULSION secondary to EtOH withdrawal, decerebrate posturing. Dx includes hepatic encephalopathy w/hepatic coma (ACUTE BRAIN SYNDROME), UGI bleed (GI HEMORRHAGE), coagulopathy (COAGULATION DISORDER) & LIVER FAILURE. On same day admitted to hosp. During PA&A-line placement, developed acute RESPIRATORY DISTRESS. Transfer'd (10/16/93) to 2nd hosp for possible liver transplant. Hosp course includes abx, GCSF, "benzos" & switch of DILANTIN® to phenobarb. D/C summary on 12/14/93 listed secondary dx of DILANTIN® toxicity & psoriasis.				9. NDC # - for product problems only (if known)			
6. Relevant tests/laboratory data, including dates  10/15/93 on admission: Hct=28.3, plt=60, WBC=20, BUN=54, Cr=1.5, gluc=129, Na=148, K=4.9, Cl=108, CO2=16, EtOH=11, ammonia=104, PT=21.9, PTT=36.5, GOT=1704, GPT=500, alk phos=108, Tbili=4.3, Dbili=2.9, amylase=63, Ca=8.3, EGD showed evidence of (see sect B7)				10. Concomitant medical products and therapy dates (exclude treatment of event) unspecified antihistamines and hydrochlorothiazide			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal u. s. function, etc.) history of HTN, alcoholic cirrhosis, anemia, & EtOH abuse; NKDA (sect B6 cont) upper GI bleed, cardiac output=12.7, Cl=6.5, SVR=830, CVP=8, PAD=16, WP=8; Final Lab determination at 2nd institution: Hgb=9.0, Hct=26.5, WBC=6.4, Na=139, K=5, Cl=107, CO2=20, BUN=20, Cr=0.9, gluc=145; 10/16/93: AST=1389, alk phos=166; 10/17/93 T Bili=14.2; 12/13 T Bili=3.1, alk phos=166				G. All manufacturers			
				1. Contact office - name/address (& mixing site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-233-7820	
				4. Date received by manufacturer (m/d/y) 12/31/97		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer  health professional ( ) professional ( ) user facility  company representative ( ) distributor (X) other: attorney	
				6. # IND, protocol #		7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	
				8. Adverse event term(s) HEMATEMESIS EDEMA FACE CONVULSION HEMORRHAGE GI BRAIN SYND ACUT COAGULATION DIS LIVER FAILURE RESPIRATORY DIS			
				9. Mfr. report number 0932121A			
				E. Initial reporter			
				1. Name, address & phone # [REDACTED]			
				2. Health professional? ( ) Yes (X) No		3. Occupation attorney	
				4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			



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