

Individual Safety Report



3546391-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



McNeil Consumer Healthcare
 1700 North 15th Street
 Ft. Washington, PA 19034-2299

Approved by FDA on 11/19/00

MDR report #
UP/Dist report #
FDA use only

Page ___ of ___

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In confidence	2. Age at time of event: 7 mo Date of birth:	3. Sex (X) female () male	4. Weight lbs or 8.6 kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Infants' TYLENOL Drops #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 approx 375mg/kg over 24h #2		3. Therapy dates (if unknown, give duration) from/to for best estimate #1 approx 2/26/00-2/27/00 #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 fever associated w/ routine illness #2		5. Event abated after use stopped or dose reduced #1 (X) Yes () No () N/A #2 () 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		7. Exp. date (if known) #1 unknown #2	
3. Date of event (mo./day/yr) 2/28/00		4. Date of this report (mo./day/yr) 05/05/00		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
5. Describe event or problem Physician report of ACCIDENTAL OVERDOSE allegedly associated with the use of Infants' TYLENOL® acetaminophen Drops in a 7 mo old female pt. According to physician, over an 18-24 hr period between approximately 2/26/00 and 2/27/00, a patient was accidentally given doses of Infants' TYLENOL® Drops in teaspoonfuls, rather than dropperfuls, to treat a fever associated w/ a routine illness. The total dose given was reportedly 375 mg/kg. On 2/28/00, the patient was reportedly admitted to hospital and experienced LIVER FAILURE. Physician reports patient was in ICU for an unspecified amount of time. The patient was discharged on an unspecified date and has reportedly recovered. Details of patient's clinical course and treatment were not provided. Addl info rec'd 5/5/00: Med rec indicate pt was admitted to ICU for an accidental TYLENOL overdose, approx 375 mg/kg over a 24-hour time period. Pt presented w/ fussiness and mental status changes (THINKING ABNORMAL). Pt was treated w/ a full course of MUCOMYST® during the first 3 days of (See Sect B7)				9. NDC # - for product problems only (if known) -			
6. Relevant tests/laboratory data, including dates 2/28/00 on adm temp=37.8, pulse=110, RR=32, BP=105/60; 2/29/00 US revealed hepatomegaly, hepatic parenchymal edema; 3/1/00 AST=9384, ALT=5768, PT=30, PTT=52.5; 3/4/00 ammonia=68; prior to d/c AST=390, ALT=1954, CBC=WNL				10. Concomitant medical products and therapy dates (exclude treatment of event) none (Sect B7 Cont) & 52.5 respectively. Prior to d/c, AST=390, ALT=1954 and ammonia=68. Otherwise, all other liver function tests normalized. D/c dx=acetaminophen hepatotoxicity.			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) none (Sect B5 Cont) hospitalization. On 2/29/00, an US showed HEPATOMEGALY & hepatic parenchymal edema. Liver function tests peaked on 3/1/00, AST=5768 (SGOT INCREASED) & ALT=9384 (SGPT INCREASED) but continued trending downward. Peak PT & PTT on 3/1/00 was 30 (PROTHROMBIN INCREASED) (See Sect C10)				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) 05/05/00		3. Report source (check all that apply) () foreign () study () 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 OTC product (X) Yes	
				7. Type of report (check all that apply) () 5-day () 15-day () 10-day (X) periodic () Initial (X) follow-up # 1		8. Adverse event term(s) OVERDOSE ACCID LIVER FAILURE THINKING ABNORM HEPATOMEGALY SGOT INCREASED SGPT INCREASED PROTHROMBIN INC	
				9. Mfr. report number 1324632A		E. Initial reporter	
				1. Name, address & phone # [REDACTED] [REDACTED] [REDACTED] AUG - 9 2000			
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			