

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Individual Safety Report



3128138-X-00-01

Page ___ of ___

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient Identifier Case 184 In confidence	2. Age at time of event: or _____ Date of birth: _____ 3 yrs	3. Sex () female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Unknown acetaminophen product #2 _____		2. Dose, frequency & route used #1 unknown dose, po #2 _____	
B. Adverse event or product problem				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown #2 _____		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A	
				4. Diagnosis for use (indication) #1 unknown #2 _____		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				6. Lot # (if known) #1 Unknown #2 _____		7. Exp. date (if known) #1 Unknown #2 _____	
2. Outcomes attributed to adverse event (check all that apply)				9. NDC # - for product problems only (if known)			
(X) death (m/d/y) unknown () life-threatening (X) hospitalization - initial or prolonged				() disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:			
3. Date of event (m/d/y) unknown		4. Date of this report (m/d/y) 08/28/98		10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
5. Describe event or problem				G. All manufacturers			
Literature report (Am J Emerg Med 1997;16(5):443-497) from Annual Report of the American Association of Poison Control Centers TESS database of human exposure cases reported by 66 participating centers during 1997. Case 184, a 3 yo boy w/a hx of a fall was evaluated in ED for lethargy (SOMNOLENCE). The possibility of abuse was considered because of multiple injuries & presence of opiates in the urine. Lab data revealed a blood glucose level of less than 10 mg/dl (HYPOGLYCEMIA), coagulopathy (COAGULATION DISORDER) & LIVER FAILURE. Further hx disclosed the child had been given both over-the-counter & prescription formulations containing acetaminophen over the past 4-5 days. A comprehensive drug screen was positive for pseudoephedrine, dextromethorphan & codeine. Serologic evaluation excluded viral causes of liver failure. The child rec'd IV NAC & was transferred for liver transplantation. However, his condition rapidly deteriorated & he died (DEATH) 3 days after presentation. Centrilobular necrosis was present on postmortem. No further info was provided.				1. Contact office - name/address (& mfring 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) 08/27/98		5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
6. Relevant tests/laboratory data, including dates				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #			
Labs: Blood glucose level of less than 10 mg/dL, ALT=2453 U/L, PT=32.6 seconds, Bili=3.4 mg/dL, Serum acetaminophen level=11 ug/mL, comprehensive drug screen was positive for pseudoephedrine, dextromethorphan & codeine				8. Adverse event term(s) SOMNOLENCE HYPOGLYCEMIA COAGULATION DIS LIVER FAILURE DEATH			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				9. Mfr. report number 1026874A			
				E. Initial reporter			
				1. Name, address & phone # Toby L. Litovitz, MD Amer. Assoc of Poison Control Centers 3201 New Mexico Ave. Washington DC 20016		202-362-3863 SEP 10 1998	
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			