



09-FEB-1998-0972

McNEIL

McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON

Individual Safety Report



3026110-1-00

Page ___ of ___

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In Confidence	2. Age at time of event: 33 yrs or Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2 TYLENOL PM		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 several months #2 unknown	
2. Dose, frequency & route used #1 2, q4h, po #2 unknown				4. Diagnosis for use (indication) #1 back pain #2 unknown		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
B. Adverse event or product problem				6. Lot # (if known) #1 Unknown #2 Unknown		7. Exp. date (if known) #1 Unknown #2 Unknown	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
2. Outcomes attributed to adverse event (check all that apply) () death (m/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
3. Date of event unknown (m/day/yr)		4. Date of this report 01/21/98 (m/day/yr)		G. All manufacturers			
5. Describe event or problem Verbal report received via media of a presumed TYLENOL OVERDOSE allegedly associated with the use of a TYLENOL acetaminophen product and one of our TYLENOL PM products. According to reporter, a 33 year old female patient took two TYLENOL every 4 hours for several months for back pain. Patient may have also taken TYLENOL PM. As of 1/20/98, the patient was in the hospital awaiting a liver transplant (LIVER DAMAGE) due to "presumed TYLENOL overdose". Reporter unable to provide any additional information regarding event. Unable to request further information since reporter unable to provide name, address, or telephone number of treating physician or patient.				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	
8. Relevant tests/laboratory data, including dates unknown				4. Date received by manufacturer (m/day/yr) 01/20/98		3. Report source (check all that apply) () foreign () study () literature () consumer () health professional () user facility () company representative () distributor (X) other: Reporter	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				6. If IND, protocol #		5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
				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) OVERDOSE LIVER DAMAGE	
				9. Mfr. report number 0920462A			
				E. Initial reporter			
				1. Name, address & phone # [REDACTED]			
2. Health professional? () Yes (X) No		3. Occupation News Reporter		4. Initial reporter also sent report to FDA () Yes () No (X) No			



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.