

RECEIVED AT DRUG SAFETY SURVEILLANCE



07-MAY-1998-0429

McNEIL

3L CONSUMER PRO
FORT WASHINGTON

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Individual Safety Report



3074411-3-00

Approved by FDA on 11/15/93

My report #

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or _____ 57 yrs Date of birth: _____	3. Sex () female (X) male	4. Weight unk lbs or kgs
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B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	2. Outcomes attributed to adverse event (check all that apply)
3. Date of event (mo/day/yr) 2/95	4. Date of this report (mo/day/yr) 04/21/98

5. Describe event or problem

Consumer alleges that the use of an Extra Strength TYLENOL® acetaminophen product was associated with HEPATITIS. Consumer reports taking 1000 mg of TYLENOL 3-4 times/day as needed for pain & headache. In 2/95, unspecified lab tests were obtained & consumer was reportedly diagnosed w/Hepatitis C. Since diagnosis consumer discontinued use of alcohol & subsequently in 4/96 discontinued use of all medications including TYLENOL. In 3/98, unspecified lab tests reportedly confirmed diagnosis of Hepatitis C. According to consumer, physician does not attribute Hepatitis C to use of TYLENOL. As of 3/98, consumer has refused treatment & has not kept last 3 or 4 appointments w/physician. Addl info rec'd 4/20/98: medical data follow-up form completed by consumer indicates event required hospitalization. Consumer reported taking 500 mg TYLENOL 2-4 times/day as needed for approx. 31 yrs. In 2/95, consumer went to ER & was hospitalized. Diagnosis reported as non-A, non-B hepatitis (toxic LIVER DAMAGE). Info regarding treatment received not provided.

6. Relevant tests/laboratory data, including dates

2/95 unspecified lab tests revealed Hepatitis Non-A, Non-B; 3/98 second unspecified lab tests confirmed diagnosis of Hepatitis C

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

history of high blood pressure, intolerance to dairy products, unspecified stomach problems, "use to drink beer" but discontinued alcohol use in 2/95; allergic to aspirin

C. Suspect medications

1. Name (give labeled strength & mfr/labeler, if known)	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 Extra Strength TYLENOL product	#1 1965-1996; approx 31 yrs
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 pain, headache, muscle aches, fever	#1 () Yes () No (X) N/A
#2	#2 () Yes () No () N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
9. NDC # - for product problems only (if known)	8. Event reappeared after reintroduction
	#1 () Yes () No (X) N/A
	#2 () Yes () No () N/A
10. Concomitant medical products and therapy dates (exclude treatment of event)	
unknown	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo/day/yr) 04/20/98	3. Report source (check all that apply)
6. # IND, protocol #	() foreign () study () literature (X) consumer () health professional () user facility () company representative () distributor () other:
7. Type of report (check all that apply)	(A) NDA # 17-552
() 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 1	IND # PLA # pre-1938 () Yes OTC product (X) Yes
9. Mfr. report number	8. Adverse event term(s)
0957341A	HEPATITIS LIVER DAMAGE

E. Initial reporter

1. Name, address & phone #	2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
	() Yes () No		() Yes () No () 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