



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

Page ___ of ___

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: 49 yrs
3. Sex: () female (X) male
4. Weight: unk lbs or kgs

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):
() death (mo/day/yr)
() life-threatening
(X) hospitalization - initial or prolonged
() disability
() congenital anomaly
() required intervention to prevent permanent impairment/damage
() other:

3. Date of event: 7/5/95 (mo/day/yr)
4. Date of this report: 11/08/99 (mo/day/yr)

5. Describe event or problem
Amended Complaint alleges that use of an Extra Strength TYLENOL acetaminophen product & other unspecified TYLENOL OTC products was associated w/LIVER DAMAGE. According to Amended Complaint, pt w/hx of regular & sometimes heavy ETOH consumption used an Extra Strength TYLENOL product & other unspecified TYLENOL products w/in limits of amts suggested for several mos prior to 7/95. From 7/9/95-7/13/95, pt was admitted hospital for a GI bleed (GASTROINTESTINAL HEMORRHAGE) from esophageal varices (ESOPHAGEAL HEMORRHAGE) & severe ANEMIA caused by the GI bleed. From 4/5/98-5/9/98, pt admitted for a liver transplant that was complicated by abdominal bile duct leak (GI DISORDER) & NECROSIS. Addl info rec'd 11/4/99: Med records indicate pt was admitted on 7/9/95 because of several days of DIZZINESS, light headedness. Pt reportedly stated that on 7/4/95 he "drank alot", & following that experienced several days of bilious vomiting & progressive weakness. Pt stated he had noticed "dark" stool & over the past few days the vomiting was also (See Sec B7)

6. Relevant tests/laboratory data, including dates
7/9/95(ER):AST=67,ALT=20,AP=80,GGT=227,TBili=2.8,Hgb=7.0,Hct=19.7,PLT=128,WBC=16.4,APTT=33,PT=15.7,INR=1.66,noEtOHorAPAP levels drawn;(ADM):BP=100/50,P=118;7/11/95(0403):ACT=83,ALT=31,AP=74,GGT=165,TBili=4.3;7/13/95(0500):Hgb=10.5,Hct=29.2

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
for approx 20 yrs, pt drank up to one-fifth of ETOH or more daily; h/o liver problems due to ETOH abuse, DM (Sect B5 cont):"dark". Pt had been taking PEPTO-BISMOL & diabetes med. Some banding of grade 2 varices performed. D/c dx: s/p significant GI bleed;severe anemia; abnormal LFT's w/ PT INCREASED, decreased albumin, & increased bili (See Sec C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Extra Strength TYLENOL acetaminophen product
#2 other unspecified TYLENOL OTC products
2. Dose, frequency & route used
#1 unknown dose, po
#2 unknown dose, po
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 several months prior to 7/95
#2 unknown dates
4. Diagnosis for use (indication)
#1 unknown
#2 unknown
5. Event abated after use stopped or dose reduced
#1 () Yes (X) No () N/A
#2 () Yes (X) No () N/A
6. Lot # (if known)
#1 Unknown
#2 unknown
7. Exp. date (if known)
#1 Unknown
#2 unknown
8. Event reappeared after reintroduction
#1 () Yes () No (X) N/A
#2 () Yes () No (X) N/A
9. NDC # - for product problems only (if known)
10. Concomitant medical products and therapy dates (exclude treatment of event) prior to 7/95: diabetes med, PEPTO-BISMOL, no TYLENOL listed (Sec B7 cont):most likely secondary to alcohol abuse;significant alcohol abuse; DM. From 4/5/98-5/9/98, pt admitted for liver transplant due to ESLD & alcoholic liver cirrhosis.

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
3. Report source (check all that apply)
() foreign
() study
() literature
() consumer
(X) health professional
() user facility
() company representative
() distributor
() other:
4. Date received by manufacturer (mo/day/yr)
11/04/99
5. (A) NDA # 19-872
IND #
PLA #
pre-1938 () Yes
OTC product (X) Yes
6. If IND, protocol #
7. Type of report (check all that apply)
() 5-day (X) 15-day
() 10-day () periodic
() Initial (X) follow-up # 1
8. Adverse event term(s)
LIVER DAMAGE HEM ESOPH
HEMORRHAGE GI ANEMIA
GI DISORDER NECROSIS
DIZZINESS PROTHROMBIN INC
9. Mfr. report number
1251394A

E. Initial reporter

1. Name, address & phone #
[redacted]
[redacted] Street
[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.