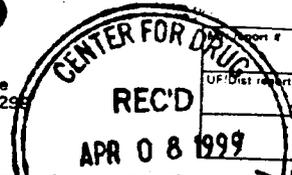




\*3235060-7-00-01\*

McNeil

Consumer Healthcare  
McNeil Consumer Healthcare  
Fort Washington, PA 19034-2255



Report #  
UP Dist report #  
FDA use only

Page \_\_\_ of \_\_\_

A. Patient information

1. Patient identifier: 01597779  
2. Age at time of event: 38 yrs  
3. Sex: ( ) female (X) male  
4. Weight: 76 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):  
(X) death (5/24/93)  
(X) hospitalization - initial or prolonged  
3. Date of event: 4/24/93  
4. Date of this report: 03/29/99

C. Suspect medication(s)

1. Name (give labeled strength, concentration, or labeler, if known):  
#1 Extra Strength TYLENOL  
2. Dose, frequency & route used:  
#1 1-2 grams, daily, po  
3. Therapy dates (if unknown, give duration):  
#1 unknown dates or duration  
4. Diagnosis for use (indication):  
#1 assorted pains  
5. Event abated after use stopped or dose reduced:  
#1 ( ) Yes ( ) No (X) N/A  
6. Lot # (if known): #1 Unknown  
7. Exp. date (if known): #1 Unknown  
8. Event reappeared after reintroduction:  
#1 ( ) Yes ( ) No (X) N/A  
9. NDC # - for product problems only (if known):  
10. Concomitant medical products and therapy dates (exclude treatment of event):  
liver consult: ECOTRIN (2T qd); Sec B6 cont: pseudocyst formation; organizing fibrinopurulent peritonitis; diffuse alveolar damage; portal cirrhosis-severe; acute bronchopneumonia-LUL; intravascular nucleated RBC's w/in renal vasa recta; c/w ATN

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: 215-273-7820  
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: 03/29/99  
5. (A) NDA # 17-552  
IND #  
PLA #  
pre-1938 ( ) Yes  
OTC product (X) Yes

8. Adverse event term(s):  
DEATH PANCREATITIS  
LIVER FATTY ASCITES  
KIDNEY FAILURE RESPIRATORY DIS  
SEPSIS COAGULATION DIS

E. Initial reporter

1. Name, address & phone #:  
[Redacted], MD  
[Redacted] Medical Ctr  
[Redacted]  
2. Health professional? (X) Yes ( ) No  
3. Occupation: physician  
4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

Notification via litigation of case summaries provided by MD/co-author of lit report (N Engl J Med 1997;337:1112-7). Info provided based on extracted data from med rec of pts hosp for APAP ingestion b/t 1/1/92 & 4/30/95. According to data, 38yo pt w/ h/o regular ETOH use adm to hosp c/o abd pain. Pt took 2-4 ES TYLENOL qd. Pt died (DEATH) on 5/24/93. Addl info rec'd 3/29/99: med rec indicate, pt adm (4/24/93) c/o 2d h/o abd pain, n/v. Transfer'd to 2nd hosp (4/28/93) w/ d/o acute PANCREATITIS. Pt did well initially. Radiology studies showed fatty changes in liver (FATTY LIVER), ASCITES, & bil pleural effusions. Paracentesis: c/w spontaneous bacterial peritonitis. Tx w/ ABX. On 5/13/93, recurrence of abd pain w/ inc WBC, pancreatic enzymes & fever. Developed hepatic encephalopathy. To MICU due to oliguric RENAL FAILURE, SEPSIS & worsening resp status (RESPIRATORY DISORDER). Pt intubated, rec'd med to inc BP & urinary output. Pt had coagulopathy (COAGULATION DISORDER) & became hypotensive & died (5/24/93). Autopsy Report - Cause of DEATH: acute pancreatitis.

6. Relevant tests/laboratory data, including dates:  
4/24/93: WBC=13.1, H/H=13.4/38.5, NA=136, K=3.2, Cl=96, BUN=3, Cr=0.7, AST=235, ALT=73, AP=382, Tbili=6.7; 4/30/93: T=38.1, WBC=16.8, Plt=252, GGT=479, NH3=54, Hep serology=NR, paracentesis=coag(-) staph; 5/17/93: pH=7.29, PCO2=49, PO2=78, O2Sat=94; (See sec B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
T&A, sinusitis, hx ETOH abuse (10 beers/d x 7 yrs), tobacco (2 ppd x 15 yrs), no h/o pancreatitis, gb dz or inc lipids; black stool 1 mo PTA; NKDA; Sec B6 cont: 5/24/93 WBC=82.1, H/H=10.5/31.9, PT=18.7, PTT=57.8, Na=129, K=5.1, Cl=89, BUN=97, Cr=7.2, AP=209, AST=131, Tbili=11.9, amy=264, lipase=467, 5/25/93: Autopsy Report: principal dx: resolving acute pancreatitis w/ (See sec C10)