Individual Safety Report

3235064-4-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page ____ of ____

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
APR 0 8 1999
CDR

Approved by FDA on 11/15/93

Mfr report #

UK report #

FDA use only

A. Patient information

1. Patient identifier: 652380 In confidence
2. Age at time of event: 40 yrs or Date of birth: [redacted]
3. Sex: (X) female ( ) male
4. Weight: lbs or 42 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 (mo/day/yr): 5/20/92

4. Date of this report (mo/day/yr): 03/30/99

5. Describe event or problem

Notification via litigation of case summaries provided by MD/co-author of lit report(N Engl J Med 1997;337:1112-1117). Info provided based on extracted data from med rec of pts hosp for acetaminophen ingestion b/t 1/1/92 & 4/30/95. According to extracted data, pt adm for TYLENOL OD (ACCIDENTAL OVERDOSE) & ETOH PANCREATITIS. Addl info rec'd 3/29/99: Med rec indicate pt w/hx of ETOH abuse, pancreatitis, & infected pseudocyst presented to ER on 5/20/92 w/6d h/o "feeling funny" & 3d h/o abd pain.Pt reportedly took large amt of TYLENOL for pain &drank more than her usual 3 12oz beers/d.Adm to MICU (5/21/99) for pancreatitis w/pseudocyst & GIB (GASTROINTESTINAL HEMORRHAGE). Pt found to have ENCEPHALOPATHY & SEPSIS. 5/21/92 GI/liver consult:fulminant hep failure (LIVER FAILURE) sec to Tylenol superimposed on chr ETOH & nutritional depletion (glutathione). Rec'd MUCOMYST®x18 doses & intub for ARDS (RESPIRATORY DISORDER). Rec'd ext drainage of inf pseudocyst & became hypotensive(HYPOTENSION) during procedure. D/c'd home on 7/1/92. Principal dx: pan pseudocyst.

6. Relevant tests/laboratory data, including dates

5/20/92 H/H=9.2/32.1,Na=130,K=5.7,Cl=89,CO2=12,SCr=3.0,AST=22560,AP=239,TBili=3.4,Amy=508,WBC=19.4,PT/PTT=25.0/39.2, gluc=107,BUN=19,guaiac(+),gastrin=179,CPK=207,CK-MB=5,aHAV-IGM(-),HBsAg(-),aHBc(-);ABG:pH=7.28,pCO2=19, (See Sec B7)

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

h/o chr etoh abuse (3-6 beers/day) w/last drink 3 d PTA,possible IVDA; decr food intake since 5 d PTA; h/o pancreatitis NKDA Sec B6 cont:pO2=132,HCO3=9,O2sat=98; 5/21/92 PT=18.9, PTT=42.7,TP=5.4,NH3=134,ALT=1169;(1230) APAP(over 24hrs post ingestion)=less than 1;(2130) APAP=1;drug screen(-); (0545) blood(+)S.aureus;5/23/92 GGT=439;pancr fluid (See Sec C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/code if known)
#1 Extra Strength TYLENOL product
#2

2. Dose, frequency & route used
#1 unknown dose, prn, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown duration
#2

4. Diagnosis for use (indication)
#1 abdominal pain
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 unknown
#2

7. Exp. date (if known)
#1 unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
none Sec B7 cont:(+)S.aureus; 5/25/92 sputum (+) C.albicans, TBili=9.8; 5/29/92 PTT=71.7,WBC=36.9; 5/30/92 Alb=1.6; 6/20/92 AST=62,LD=311,TBili=0.8; 6/27/92 ALT=36; 6/30/92 GGT=229; 7/10/92 WBC=5.7,H/H=11.3/35.7,Alb=2.8,TP=6.5

G. All manufacturers

1. Contact office - name/address (& mfring site for DSS)
McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

APR 0 9 1999

RECEIVED
APR 0 8 1999
ADVERSE EVENT REPORTING SYSTEM

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 (mo/day/yr): 03/29/99

5. (A) NDA # 17-552
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)
OVERDOSE ACCID
PANCREATITIS
HEMORRHAGE GI
ENCEPHALOPATHY
SEPSIS
LIVER FAILURE
RESPIRATORY DIS
HYPOTENSION

9. Mfr. report number: 0903788A

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

FDA
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.