

Individual Safety Report



3547365-8-00-014

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page ___ of ___

Approved by FDA on 11/18/93

Mfr report # _____

UP/Dist report # _____

FDA use only

A Patient information

1. Patient identifier unknown in confidence	2. Age at time of event: 3 yrs or Date of birth:	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
(X) required intervention to prevent permanent impairment/damage
() other:

3. Date of event (mo/day/yr) unknown

4. Date of this report (mo/day/yr) 05/04/00

5. Describe event or problem

Literature report (Arch Pediatr Adolesc Med 2000;154:346-50) of a retrospective chart review of pts examined because of acetaminophen OVERDOSE from 1/1/88-12/31/97 in 2 regional urban pediatric hospitals. Data from 322 pts were obtained: ingestions were intentional in 140 & unintentional in 172. Another 10 cases represented dosing errors with therapeutic intent. Twenty-seven pts had hepatocellular injury defined as an elevation of serum aminotransferase levels greater than 2 times the age adjusted upper limit of the reference range. Of these, 4 had severe hepatotoxic effects (aminotransferase levels exceeding 1000 U/L, as well as clinical evidence of altered mental status noted in the chart by the clinician and/or coagulopathy in addition to hepatocellular injury) & 1 pt died. No pts underwent liver transplantation. One pt who developed hepatocellular injury (LIVER DAMAGE) was a 3 year-old male who accidentally ingested 163 mg/kg of an unspecified acetaminophen product. Pt presented 8 hrs post-ingestion & was treated (See Sect B7)

6. Relevant tests/laboratory data, including dates

unspecified time post-ingestion: peak AST=966 U/L

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

unknown

(Sect B5 cont) w/ MAC. Peak AST level was 966 U/L (SGOT INCREASED) at an unspecified time post-ingestion. No further information was provided regarding pt's clinical course.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unspecified acetaminophen product
#2 _____

2. Dose, frequency & route used

#1 163 mg/kg, once, po
#2 _____

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

#1 unknown date; 1 day
#2 _____

4. Diagnosis for use (indication)

#1 accidental ingestion
#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)

unknown

G All manufacturers

1. Contact office - name/address (& mfrng 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
(X) literature
() consumer
(X) health professional
() user facility
() company representative
() distributor
() other:

4. Date received by manufacturer (mo/day/yr) 05/01/00

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 () 15-day
() 10-day (X) periodic
(X) initial () follow-up # _____

8. Adverse event term(s)

OVERDOSE LIVER DAMAGE
SGOT INCREASED

9. Mfr. report number

1357534A

E Initial reporter

1. Name, address & phone #

Sarah W. Alander, MD
Children's Mercy Hospital
2401 Gilham Road
Kansas City, MO 64108

2. Health professional?

(X) Yes () No

3. Occupation

physician

4. Initial reporter also sent report to FDA

() Yes () No (X) Unk

AUG - 9 2000



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

00 001031