

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

**McNEIL**

McNEIL CONSUMER PR  
FORT WASHINGTON

Individual Safety Report



Approved by FDA on 11/16/93

Page 0

## A. Patient information

1. Patient identifier Case 608 In confidence	2. Age at time of event: or 10 mo 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) unknown	4. Date of this report (mo/day/yr) 09/02/98

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 Unknown acetaminophen product #2	2. Dose, frequency & route used #1 unknown dose, po #2	3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 several days #2
4. Diagnosis for use (indication) #1 febrile illness #2	5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	6. Event reappeared after reintroduction #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. Concomitant medical products and therapy dates (exclude treatment of event) unknown (Sect. B.7 cont) acetaminophen level was less than 10, hepatic transaminases were in the 2000 U/L range, PT=14 seconds, INR=1.5

## G. All manufacturers

1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	2. Phone number 215-233-7820
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) 08/27/98
5. (A) NDA # 19-872 IND # PLA # pre-1838 ( ) Yes OTC product (X) Yes	6. Adverse event term(s) SOMNOLENCE HEMATEMESIS DEHYDRATION TACHYCARDIA HEPATOMEGALY ANURIA RESPIRATORY DIS DEATH
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	8. Mfr. report number 1028776A

Describe event or problem

Literature report (Am J Emerg Med 1997;16(5):443-497) from Annual Report of the American Association of Poison Control Centers TESS database of human exposure cases reported by 66 participating centers during 1997. Case 608, pt presented w/ hx of excessive use of iron & acetaminophen over several days for a febrile illness. Pt was lethargic (SOMNOLENCE) had decreased oral intake & brownish-red emesis. Pt's condition worsened to include: bloody vomitus (HEMATEMESIS), DEHYDRATION, TACHYCARDIA, HEPATOMEGALY, decreased urine output. Pt was intubated, sedated & paralyzed. Tx included: neomycin, lactulose, double volume exchange transfusion, IV NAC, deferoxamine, furosemide & whole bowel irrigation w/PEG. Resp status & cardiovascular functions declined, so dopamine, dobutamine, epinephrine, high freq ventilation were started. ANURIA developed on Day 4. Extracorporeal membrane oxygenation to treat ARDS (RESPIRATORY DISORDER). Pt died (DEATH) on hosp day 5. An autopsy indicated that death resulted from multiple organ failure caused by iron & acetaminophen toxicity.

8. Relevant tests/laboratory data, including dates

hemoglobin=9.7g/dL, ALK=10900 U/L, LDH=32010 U/L, serum iron=274 ug/dL, serum iron=274 ug/dL, serum acetaminophen level= 25 ug/mL; blood, cerebrospinal fluid, hepatitis screens & cultures were negative; (See Sect. B.7)

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

unspecified febrile illness (Sect. B.6 cont) 2nd hosp day: Pulse=165 beats/min, B/P= 120/60 mmHg, Resp rate=26 breaths/min, serum iron=224 ug/dL, acetaminophen level=16 ug/mL, hemoglobin=8.5 g/dL, ALT=8606 U/L, AST=16901 U/L, PT=23 seconds, INR=2.44, PTT=48.8 seconds, ammonia=154ug/dL; 3rd osp day: serum iron=80 ug/dL, (See Sect. C.10)

## E. Initial reporter

1. Name, address & phone # Toby L. Litovitz, MD Amer Assoc of Poison Control Centers 3201 New Mexico Ave., Suite 310 Washington DC. 20016	2. Health professional? (X) Yes ( ) No	3. Occupation physician	4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk
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