

Individual Safety Report



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

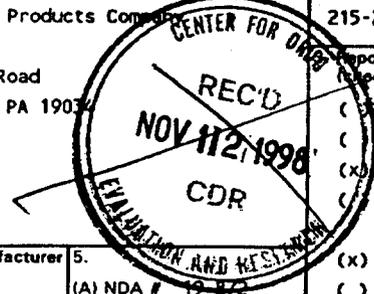
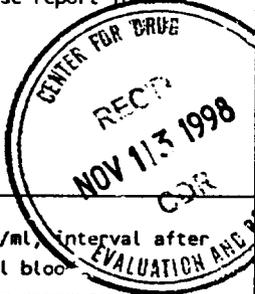
CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient Identifier Case 236 In confidence	2. Age at time of event: or 43 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown acetaminophen product #2 phenobarital			
B. Adverse event or product problem				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 unknown #2 unknown	
				4. Diagnosis for use (indication) #1 unknown #2 unknown		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				6. Lot # (if known) #1 Unknown #2 unknown		7. Exp. date (if known) #1 Unknown #2 unknown	
2. Outcomes attributed to adverse event (check all that apply) () death (unknown mo/day/yr) () life-threatening () hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A			
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 11/09/98		9. NDC # - for product problems only (if known) - - -			
5. Describe event or problem Literature report (Am J Emerg Med 1998;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. Information provided in line listing indicates Case 236 was a 43 year old who ingested an unknown amount of an acetaminophen product and phenobarbital and died (DEATH). Acetaminophen blood concentration was reported to be 12 mcg/ml greater than 24 hours after exposure. Phenobarbital blood concentration, was reported to be 22.7 mcg/ml at an unknown interval after exposure. Addl info rec'd 11/2/98: Case #236 received from the AAPCC 1997 case fatality data. See attached case report form provided by AAPCC.				10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by AAPCC.			
6. Relevant tests/laboratory data, including dates acetaminophen blood concentration: 12 mcg/ml, interval after exposure: greater than 24 h, phenobarbital blood concentration: 22.7 mcg/ml, interval after exposure: unknown; see attached case report form provided by AAPCC				G. All manufacturers			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) See attached case report form provided by AAPCC.				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. Date of event (mo/day/yr) unknown				4. Date received by manufacturer (mo/day/yr) 11/02/98		3. Report source (check all that apply) () foreign () study (X) literature () consumer () health professional () user facility () company representative () distributor () other:	
				6. IND, protocol #		5. (A) NDA # 19-822 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
4. 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) DEATH OVERDOSE EDEMA BRAIN LIVER FAILURE ASCITES SPLENOMEGALY PNEUMONIA RESPIRATORY DIS			
9. Mfr. report number 1046874A				E. Initial reporter			
1. Name, address & phone # Toby L. Litovitz, MD Amer Assoc of Poison Control Centers 3201 New Mexico Avenue, Suite 310 Washington, DC 20016				2. Health professional? (X) Yes () No		3. Occupation physician	
2. Health professional? (X) Yes () No				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.



CTESS FATALITY ABSTRACTS: 1997

Case Number: 236

Age: 43

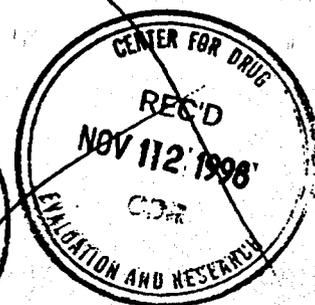
**Substances: Acetaminophen
Phenobarbital**

Chronicity: Unknown

Route: Ingestion

Reason: Unknown

Pre-Hospital Arrest: No



Abstract:

A 43 year old female with multiple medical problems including chronic pain, osteoporosis with compression fractures, nephrolithiasis, seizure disorder, and unspecified psychiatric problems, had prescriptions for morphine, phenobarbital, diazepam, nabumetone and pancrease. She arrived at a hospital after an apparent overdose of an unknown quantity of acetaminophen when a friend discovered her after a 24-hour absence. She was obtunded with partial response to naloxone. Initial vital signs were: blood pressure, 109/64 mm Hg; pulse, 94/min; respirations, 20/min; temperature, 99.0 °F. Initial laboratory studies revealed acetaminophen, > 24 hours, 12 µg/mL; aspirin, 3.8 mg/dL; ethanol, 0; AST, 1282 U/L; total bilirubin, 10 mg/dL. She was admitted for presumed morphine overdose. Her AST was 2804 U/L and ALT was 3519 U/L 13 hours after admission. Her AST was 1520 U/L and ALT 4708 U/L 32 hours after admission. Her PT was >40 sec 34 hours after admission. She then was transferred to the ICU of a tertiary care medical center. Labs on arrival were AST, 1206 U/L; ALT, 3950 U/L; total bilirubin, 14.6; and PT, 81.4 seconds. Phenobarbital level on hospital day 5 (5 hours before death) was 22.7 µg/mL. She received IV NAC from then until her death 3 days later. Initial CT on arrival to the second hospital showed no cerebral edema but repeat CT 3 days later showed diffuse cerebral edema. She was deemed a poor candidate for liver transplant by the hepatology consultant. Autopsy findings included: 1) fulminant hepatic failure with 925 gm liver showing massive necrosis; 2) ascites; 3) splenomegaly; 4) bronchopneumonia; 5) diffuse alveolar damage consistent with ARDS.