

INDIVIDUAL SAFETY REPORT



3156906-7-00-01

McNEIL

CONSUMER PRODUCTS COMPANY
ORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

A. Patient information

1. Patient identifier Case 217 In confidence	2. Age at time of event: or 44 yrs 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)
(x) death (unknown) () disability
() life-threatening () congenital anomaly
() hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage
() other:

3. Date of event (mo./day/yr) unknown	4. Date of this report (mo./day/yr) 11/04/98
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5. Describe event or problem

Literature report (Am J Emerg Med 1997;15(5):447-500) from Annual Report of the American Association of Poison Control Centers TESS database of human exposure cases reported by 67 participating centers during 1996. Information provided in line listing indicates Case 217 was a 44 year old who died (DEATH) following chronic ingestion of an unknown amount of acetaminophen, ethanol, and ibuprofen. Reason for fatal exposure listed as therapeutic error.

Additional information received 11/02/98: Case #217 received from AAPCC 1996 case fatality data. See attached case report form provided by AAPCC.

6. Relevant tests/laboratory data, including dates
acetaminophen concentration=42 ug/mL an unspecified time after exposure; see attached case report form provided by AAPCC

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
past medical history was significant for liver disease and alcohol abuse; see attached case report form provided by AAPCC

C. Suspect medication(s)

1. Name (give labeled strength & mfr./labeler, if known)	
#1 unknown ibuprofen product	
#2 acetaminophen	(See Sec C.10)
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 excessive amount	#1 over 3-4 weeks
#2 excessive amounts	#2 over 3-4 weeks
4. Diagnosis for use (indication)	
#1 therapeutic error, unidentified pain	
#2 therapeutic error, unidentified pain	
5. Event abated after use stopped or dose reduced	
#1 () Yes () No (X) N/A	
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 Unknown	#2 Unknown
8. Event reappeared after reintroduction	
#1 () Yes () No (X) N/A	
#2 () Yes () No (X) N/A	
9. NDC # - for product problems only (if known)	
-	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
unknown	
Sec C.1 cont: ethanol, unknown dose, po, unknown dates	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo./day/yr) 11/02/98	3. Report source (check all that apply)
6. If IND, protocol #	() foreign
7. Type of report (check all that apply)	() study
() 5-day (X) 15-day	(x) literature
() 10-day () periodic	() consumer
() Initial (X) follow-up # 1	(x) health professional
9. Mfr. report number	() user facility
1052480A	() company representative
5. (A) NDA # 17-463	() distributor
IND #	() other:
PLA #	
pre-1938 () Yes	
OTC product () Yes	
B. Adverse event term(s)	
DEATH	COMA
TACHYCARDIA	LIVER FUNC ABNO
LIVER FAILURE	PANCREATITIS
GASTRITIS	

E. Initial reporter

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

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

Individual Safety Report



3156906-7-00-02



AAPCC TESS FATALITY ABSTRACTS: 1996

Case Number: 217

Age: 44

Substances: Acetaminophen
ethanol
ibuprofen

Chronicity: Chronic

Route: Ingestion

Reason: Therapeutic Error

Pre-Hospital Arrest: No

Abstract:

A 44 year old male presented to the local Emergency Department (ED). On initial assessment he was unresponsive, normotensive, with a heart rate of 110 beats/min, a respiration rate of 30 breaths/min, and a temperature of 35°C. His past medical history was significant for liver disease and alcohol abuse. He was apparently on a waiting list for liver transplantation. Reportedly, over the previous 3-4 weeks, he had been taking excessive amounts of acetaminophen and ibuprofen to control some unidentified pain. Initial laboratory studies were significant for ALT, >2000 U/L; alkaline phosphates, >1000 U/L; total bilirubin, 6 mg/dL; and serum ammonia, 154 µg/dL. A blood sample, drawn about 11.5 hours after arrival to the ED, showed an acetaminophen level of 42 µg/mL. N-acetylcysteine was administered by nasal gastric tube. His condition progressively deteriorated. He died approximately 32 hours after arrival to hospital. Final diagnoses were acute on chronic hepatic failure associated with alcohol and acetaminophen toxicity, chronic pancreatitis, and gastritis.

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