



McNEIL CONSUMER PRODUCTS  
FORT WASHINGTON



\*3032553-2-00\*

19-FEB-1998-0636

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FDA Use only

<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient identifier Case 218 In confidence	2. Age at time of event: 23 yrs or Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown acetaminophen product #2 ethanol		2. Dose, frequency & route used #1 8 grams, over 24 hours, po #2 unknown	
<b>B. Adverse event or product problem</b>				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 over 24 hour period #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)				4. Diagnose for use (indication) #1 headache #2 unknown		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
2. Outcomes attributed to adverse event (check all that apply) ( ) death ( ) life-threatening ( ) hospitalization - initial or prolonged (X) death ( ) life-threatening (X) hospitalization - initial or prolonged ( ) unknown ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:				6. Lot # (if known) #1 unknown #2 unknown		7. Exp. date (if known) #1 unknown #2 unknown	
3. Date of event unknown (mo/day/yr)		4. Date of this report 02/06/98 (mo/day/yr)		9. NDC # - for product problems only (if known)			
5. Describe event or problem Case # 218 received from the ██████████ 1996 case fatality data. See attached case report form provided by ██████████				10. Concomitant medical products and therapy dates (exclude treatment of event) Sect. C1 cont'd: #3 tricyclic antidepressant (unknown dose or duration)  Sect. C10: See attached case report form provided by ██████████			
6. Relevant tests/laboratory data, including dates See attached case report form provided by ██████████				<b>G. All manufacturers</b>			
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 ██████████				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	
8. Date received by manufacturer (mo/day/yr) 01/30/98				3. Report source (check all that apply) ( ) foreign ( ) study (X) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:		5. (A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
9. Mfr. report number 0929981A				6. If IND, protocol #		7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	
9. Mfr. report number 0929981A				8. Adverse event term(s) OVERDOSE LIVER FAILURE OCCLUS MESENTER HYPOTENSION DEATH			
<b>E. Initial reporter</b>				1. Name, address & phone # ██████████, MD ██████████ Centers Suite ██████████ Ave ██████████			
2. Health professional? (X) Yes ( ) No		3. Occupation physician		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			



Facsimile Form 3600A

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



19-FEB-1998-0637



\*3032553-2-01\*

**[REDACTED] FATALITY: 1996 [REDACTED]**

**Case Number:** 218

**Age:** 23 yrs

**Substances:** Acetaminophen  
ethanol  
tricyclic antidepressant

**Chronicity:** Chronic

**Route:** Ingestion

**Reason:** Ther error

**Pre-Hospital Arrest?** No

A 23-year-old male who was a chronic alcoholic presented to the emergency department (ED) claiming to have ingested 8 grams of acetaminophen over a 24 hour period because he had a headache. The patient may also have been exposed to a tricyclic antidepressant, cannabis and opiates. At presentation, approximately 8-9 hours after the last reported dose of acetaminophen, the patient had an acetaminophen level of 41 mcg/ml. Although no laboratory values were available, the ED physician believed the patient had fulminant hepatic failure. The ED physician was concerned about possible gastrointestinal perforation and the patient was started on intravenous N-acetylcysteine (NAC) therapy. An electrocardiogram reading was not available. The patient died approximately five hours after the initial call to the poison center. Prior to his death he had received a loading dose and one maintenance dose of intravenous NAC. The cause of death was reported to the poison center as hepatic failure and intestinal ischemia secondary to hypotension.

Patient was apparently a "hard core" chronic alcoholic who died shortly after the first maintenance dose of intravenous NAC was administered. Of note is the observation that he had hypotension and bowel infarction diagnosed by unknown means at the time of his death. He stated that he took only 8 gm of acetaminophen over 24 hours while trying to combat a headache. However, no other information was available. The toxicology fellow did talk directly to the physician who was extremely harried and had just received the patient already in his pre-terminal condition.

Mental status, any labs which became available later, anything about question mark. We have scoured the record and unfortunately there is no further information.