



19-FEB-1998-0622



McNEIL CONSUMER  
FORT WASHIN

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Individual Safety Report



\*3032523-4-88\*

A. Patient Information				C. Suspect medication(s)			
1. Patient identifier Case 219 In confidence	2. Age at time of event: or 52 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 ibuprofen			
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. Let # (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) (X) death (mo/day/yr) unknown ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:				9. NDC # - for product problems only (if known)			
3. Date of event unknown (mo/day/yr)		4. Date of this report 02/06/98 (mo/day/yr)		10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by [redacted]			
5. Describe event or problem Case # 219 received from the [redacted] 1996 case fatality data. See attached report form provided by [redacted]							
G. All manufacturers							
1. Contact office - name/address (& mfrng 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) 01/30/98				5. (A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes		6. N IND, protocol #	
6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]				7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #			
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 [redacted]				9. Mfr. report number 0929983A		8. Adverse event term(s) EDEMA PERIPH      HEPATOMEGALY SPLENOMEGALY      LIVER FUNC ABNO ACIDOSIS              HYPERKALEMIA APNEA                  DEATH	
E. Initial reporter							
1. Name, address & phone # [redacted] MD [redacted] Centers [redacted] Avenue [redacted]							
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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19-FEB-1998-0623



\*3032523-4-01\*

[REDACTED] FATALITY: 1996 [REDACTED]

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Case Number: 219  
Age: 52 yrs  
Substances: Acetaminophen  
ibuprofen  
Chronicity: Chronic  
Route: Ingestion  
Reason: Int Misuse  
Pre-Hospital Arrest? No

A 52 year old woman with a history of chronic alcohol, acetaminophen and ibuprofen use presented with weakness, leg edema and an enlarged liver and spleen. Initial laboratory showed GGT 1,022 IU/L, ALT 207 IU/L, AST 240 IU/L, bicarbonate 8 mmol/l, potassium 6.0 mmol/l, and acetaminophen 7 mcg/ml. Toxicology consultation recommended starting n-acetylcysteine and ruling out aspirin, ethylene glycol, and methanol. The patient remained acidotic with a bicarbonate of 9 mmol/l and it was recommended that sodium bicarbonate be administered to correct acidosis. Thirteen hours after presentation, the patient experienced a respiratory arrest and expired. Patient was on no-code status due to preexisting cirrhosis with portal hypertension. Ethanol and methanol were negative, while ethylene glycol was not tested for.