



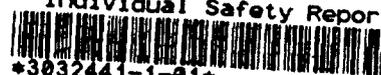
McNEIL CONSUMER PRC  
 FORT WASHINGTON

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A. Patient information				C. Suspect medication(s)			
1. Patient Identifier Case 672 In confidence	2. Age at time of event: or 37 yrs Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 acetaminophen/hydrocodone #2 aspirin			
B. Adverse event or product problem				2. Dose, frequency & route used #1 large doses, po #2 large doses, po		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2 unknown dates or duration	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 intentional abuse #2 intentional abuse		5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
2. Outcomes attributed to adverse event (check all that apply) (X) death (no/day/yr) unknown ( ) life-threatening (X) hospitalization - initial or prolonged ( ) disability ( ) 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 (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 02/06/98		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)	
5. Describe event or problem Case # 672 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted]				10. Concomitant medical products and therapy dates (exclude treatment of event) Sect. C1 cont'd: #3. cocaine (abusing as a binger, unknown duration)  Sect. C10: See attached case report form provided by [redacted]			
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) 01/30/98				5. (A) NOA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes		6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]	
6. If IND, protocol #				7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) initial ( ) follow-up #		8. Adverse event term(s) COMA                      FEVER HEART ARREST          DEATH EDEMA LUNG              EDEMA BRAIN FIBRO MYOCARD          LIVER CIRRHOSIS	
9. Mfr. report number 0929649A				E Initial reporter			
1. Name, address & phone # [redacted] MD [redacted] Centers Suite [redacted] Avenue [redacted]				2. Health professional? (X) Yes ( ) No		3. Occupation physician	
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]				4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk			



19-FEB-1998-0587



\*3032441-1-01\*

 FATALITY: 1996 

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Case Number: 672

Age: 37 yrs

Substances: Cocaine  
acetaminophen/hydrocodone  
aspirin

Chronicity: Acute

Route: Ingestion

Reason: Int Abuse

Pre-Hospital Arrest? No

37 year old male arrived at the ED comatose and unresponsive. He had not been seen for the previous 24 hours. The patient apparently had taken large oral doses of hydrocodone/acetaminophen, acetaminophen, aspirin and had apparently been abusing cocaine as a binger. Two doses of naloxone was given without response. The patient continued to deteriorate in the ED, was intubated and transferred to the ICU. In the ICU his temperature rose to 108 degrees F and he suffered a cardiac arrest and expired. Urine toxicology screen was positive for cocaine and opiates. Postmortem toxicologic analysis revealed blood benzoylecgonine of 1693 ng/ml and urine benzoylecgonine at 60015 µg/ml. The cause of death was determined to be complications of acute cocaine intoxication with marked hyperthermia. Also present was pulmonary and cerebral edema, focal moderate interstitial myocardial fibrosis and cirrhosis of the liver. The toxicologic analysis was negative for other drugs of abuse and negative for alcohol.