



19-FEB-1998-0670



McNEIL CONSUMER PF
FORT WASHINGTON

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3031720-1-00

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 196 In confidence	2. Age at time of event: 48 yrs or 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			
B. Adverse event or product problem				2. Dose, frequency & route used #1 unknown dose, po #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 chronically #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 abdominal pain/intentional misuse #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
2. Outcomes attributed to adverse event (check all that apply)				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
<input checked="" type="checkbox"/> death (m/d/y) unknown <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A		9. NDC # - for product problems only (if known)	
3. Date of event (m/d/y) unknown		4. Date of this report (m/d/y) 02/09/98		10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by			
5. Describe event or problem Case # 196 received from the 1996 case fatality data. See attached case report form provided by							
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	
4. Date received by manufacturer (m/d/y) 01/30/98						3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:	
6. If IND, protocol #						5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
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) LIVER FAILURE COMA ACIDOSIS CREATININE INC HYPOTENSION ENCEPHALOPATHY PROTHROMBIN INC DEATH	
8. Relevant tests/laboratory data, including dates See attached case report form provided by						9. Mfr. report number 0929685A	
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							
E. Initial reporter							
1. Name, address & phone # Centers Suite Avenue							
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			



Facsimile Form 3500A

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-1998-0671



3031720-1-00

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 196

Age: 48 yrs

Substances: Acetaminophen

Chronicity: Chronic

Route: Ingestion

Reason: Int Misuse

Pre-Hospital Arrest? No

A 48 year old woman with a history of alcohol abuse transfers from a community hospital in fulminant hepatic failure after taking an unknown amount of acetaminophen chronically for abdominal pain. On presentation, she was comatose and ventilator dependent. Labs on presentation included a bicarbonate of 13 mmol/l, SGPT 1,896 IU/l, SGOT 1607 IU/l, total bilirubin 4.8 mg/dl, creatinine 7.2 mg/dl, BUN 34 mg/dl, and creatinine kinase 604 U/l. Urine output of only 40 cc in the last 8 hours was noted despite 3 liters of intravenous fluids. A pulmonary artery catheter showed a systolic blood pressure of 90 to 100 mm Hg, pulmonary capillary wedge pressure of 12-13 mm Hg, CVP of 10-12 cm H₂O and CO of 5.6 L/min. An EEG done 4 hours later showed a pattern of anoxic injury and global encephalopathy. A persistent acidosis was noted along with elevation in PT to 41.5 sec with a serum ammonia of greater than 200 mg/dl. Her acidosis continued to worsen (bicarbonate of 6.5 mmol/l) and her creatinine continued to increase to 9.6 mg/dl. Decerebrate posturing was noted that progressed to flaccidity. With a persistently flat EEG, life support was withdrawn and the patient died two days after presentation.