



19-FEB-1998-0620



McNEIL CONSUMER PR
FORT WASHINGT

Page of

Individual Safety Report



3032517-9-00

A. Patient information

1. Patient Identifier Case 220 In confidence	2. Age at time of event: 24 yrs or Date of birth:	3. Sex (X) female () 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) (mo/day/yr)	() disability
() life-threatening	() congenital anomaly
(X) 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) 02/09/98
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5. Describe event or problem

Case # 220 received from the [redacted] 1996 fatality data. See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

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]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unknown acetaminophen product	
#2 lorazepam	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2.5 grams, q6h, po	#1 past 5 days
#2 unknown dose, po	#2 unknown
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 unknown	#1 () Yes () No (X) N/A
#2 unknown	
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) Sect. C1 cont'd: #3. methadone (unknown dose or duration)	
Sect C10: See attached case report form provided by [redacted]	

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
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
6. If IND, protocol #	IND #
	PLA #
	pre-1938 () Yes
7. Type of report (check all that apply)	OTC product (X) Yes
() 5-day (X) 15-day	
() 10-day () periodic	
(X) Initial () follow-up #	

8. Mfr. report number	8. Adverse event term(s)
0929992A	OVERDOSE LIVER FUNC ABNO
	HYPOTENSION ACIDOSIS
	APNEA THROMBOCYTOPENI
	HEART ARREST DEATH

E. Initial reporter

1. Name, address & phone #		
[redacted] MD [redacted] Centers [redacted]		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes () No	physician	() Yes () No (X) Unk





19-FEB-1998-0621



3032517-9-01

FATALITY: 1996

Case Number: 220

Age: 24 yrs

Substances: Acetaminophen
lorazepam
methaone

Chronicity: Chronic

Route: Ingestion

Reason: Ther error

Pre-Hospital Arrest? No

A 24-year-old woman with a history of chronic pain, depression, and a seizure disorder presented with increased drowsiness, ataxia, headaches, slurred speech, and a dry mouth. Her medications included Anafranil, amitriptyline, Mellaril, Trilafon, lithium, Tegretol, Soma, Ativan, Carafate, acetaminophen, Aleve, chelated iron, Ducolax, and methadone. She later admitted to taking five 500 mg tablets of acetaminophen every 6 hours for the past 5 days. Her laboratory studies on admission revealed, sodium, 128 mEq/L; chloride, 97 mEq/L; potassium, 4.2 mEq/L; bicarbonate, 22.2 mEq/L; creatinine, 0.6 mg/dL; SGOT, 684 IU/L; SGPT, 876 IU/L; alkaline phosphatase, 289 IU/L; acetaminophen level, 44 µg/mL; ethylene glycol, 7.6 µg/mL; tegretol, "low"; and a drugs of abuse screen that was positive for benzodiazepines and opiates. Twelve hours after admission her blood pressure had dropped to 98/52 mm Hg, pulse, 100 beats/min, and she was awake and alert but vomiting frequently. N-acetylcysteine was begun. By the second hospital day she had become lethargic and her potassium had risen to 7.2 mEq/L. Therapy with insulin and dextrose was instituted. Her SGPT had increased to 8070 IU/L; SGOT 8790 IU/L; and alk phos, 466 IU/L. An arterial blood gas showed, pH 7.36; pCO₂, 25.8 mm Hg; pO₂, 102 mm Hg; and bicarbonate, 15 mEq/L. On the third hospital day she suffered a respiratory arrest. Her arterial blood gas before intubation showed, pH 7.17; pCO₂, 42.9 mm Hg; pO₂, 87 mm Hg; and bicarbonate, 15.7 mEq/L. She had multiple petechia (platelets, 70,000/mm³) and bloody gastric emesis. Therapy included intubation, dopamine, fresh frozen plasma, insulin, atropine, and epinephrine. Following successful resuscitation her arterial blood gas on the ventilator revealed, pH 7.33; pCO₂, 30.0 mm Hg; pO₂, 303 mm Hg; and bicarbonate, 15.9 mEq/L. Later that day she developed asystole and expired. The was no postmortem examination.