



19-FEB-1998-0744



McNEIL CONSUMER F
FORT WASHINGTON

Page _____

Individual Safety Report



3031850-4-00

A. Patient information

1. Patient Identifier Case 242 In confidence	2. Age at time of event: or 42 yrs 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)
	<input checked="" type="checkbox"/> death (mo/day/yr) 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:
3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 02/06/98

5. Describe event or problem
Case # 242 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 VICODIN®	#2
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 "large doses", po	#1 chronic
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 chronic back pain	#1 () Yes () No (X) N/A
#2	#2 () Yes () No () N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
9. NDC # - for product problems only (if known)	8. Event reappeared after reintroduction
	#1 () Yes () No (X) N/A
	#2 () Yes () No () N/A
10. Concomitant medical products and therapy dates (exclude treatment of event) 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
4. Date received by manufacturer (mo/day/yr) 01/30/98	3. Report source (check all that apply)
6. If IND, protocol #	() foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:
7. Type of report (check all that apply)	5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes
() 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #	8. Adverse event term(s) OVERDOSE INTENT OLIGURIA ANEMIA CREATININE INC LIVER FUNC ABNO COAGULATION DIS RESPIRATORY DIS DEATH
9. Mfr. report number 0929700A	

E. Initial reporter

1. Name, address & phone # [redacted] MD [redacted] Centers Suite [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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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-1998-0745

Individual Safety Report
*3031850-4-06***FATALITY: 1996**

Case Number: 242
Age: 42 yrs
Substances: Acetaminophen/hydrocodone
Chronicity: Chronic
Route: Ingestion
Reason: Int Misuse
Pre-Hospital Arrest? No

Case 1485112. A 42-year-old woman with a history of chronic pain and an ileal-jejunal bypass for obesity was admitted to the hospital after being seen in the medical clinic for decreased urine output, dysarthria, weakness in her lower extremities and her usual chronic back pain for which she reportedly abused Vicodin in large doses. On admission, she was somnolent but has responded to a dose of naloxone in the ED. An initial acetaminophen level was 1 ug/ml while a repeat level twelve hours later was 17 ug/ml without any known source of acetaminophen in the previous sixteen to twenty-four hours. Her hematocrit had dropped from 30% to 20% in the previous month. Her urine output in the first twenty-four hours after admission was 30 ml; her creatinine was 2.4 mEq/L; BUN, 60 mEq/L. She was felt to be mildly malnourished. She had an enlarged liver and her protime was 19 seconds. Her liver functions were elevated; by twenty-four hours after her admission, her AST was 255; ALT, 104. Over the next several days, she required intubation and ventilator assistance and had developed DIC and ARDS. She began hemodialysis on the sixth day after admission but had multisystem failure and died on the eighth day after admission. No post-mortem was done.