



19-FEB-1998-0738

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McNEIL CONSUMER PRO
FORT WASHINGTO

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Individual Safety Report



3031844-9-00

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 246 In confidence	2. Age at time of event: or Date of birth: 35 yrs	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 VICODIN® #2 ethanol			
B. Adverse event or product problem				2. Dose, frequency & route used #1 5 tablets, q5h; 25/day #2 unknown, po		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 within the last 3 days #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 (unknown) (mo/day/yr) () 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 # 246 received from teh [redacted] 1996 case fatality data. See attached case report form provided by [redacted]				10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by [redacted]			
6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]				G. All manufacturers			
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]				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	
				4. Date received by manufacturer (mo/day/yr) 01/30/98		3. Report source (check all that apply) () foreign () study (X) literature () consumer health professional (X) 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) OVERDOSE INTENT LIVER FAILURE REACTION UNEVAL STUPOR HYDRIASIS CONVULSION HYPOTENSION DEATH	
				9. Mfr. report number 0929766A		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			



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-1998-0739

Individual Safety Report

3031844-9-00 FATALITY: 1996 

Case Number: 246

Age: 35 yrs

Substances: Acetaminophen/hydrocodone
ethanol

Chronicity: Chronic

Route: Ingestion

Reason: Int abuse

Pre-Hospital Arrest? No

This patient, with a ten year history of chronic vicodin and ethanol abuse, arrived in the emergency room, in liver failure. Prior to emergency room admission, the patient had ingested within the last three days, 25 tabs/day of Vicodin or 5 tablets Q5H. The poison center recommended a tox screen, NAC treatment, p/ptt, LFT's, and activated charcoal staggered with the NAC doses Q2H. Almost 24 hours later, the patient was still in the emergency room, vomiting the charcoal. The poison center recommended Zofran for the patient, so as to make the activated charcoal more "tolerable." Approximately 2 days after initial call, the patient was still in the emergency room in grave condition. She had multi-organ failure and dialysis was being considered. The patient was unresponsive, intubated, and being treated with Lactulose, Clonidine, and NAC. On the third day, the patient had been admitted to ICU-Unit A. The patient's pupils were fixed and dilated. She had multi-seizure activity that was treated with Valium. Dialysis treatment had been discontinued due to very low to no blood pressure. Her treatment was supportive care with no medications. She became a DNR patient. Later on, the transplant team assessed the patient. By the fourth day, the patient's condition remained the same. She was being tested to see if she met the criteria for "brain-dead." The next day, her heart was harvested for donation.