

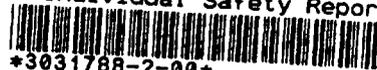


A. Patient information				C. Suspect medication(s)			
1. Patient identifier <b>Case 338</b> In confidence	2. Age at time of event: 40 yrs or Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 VICODIN® #2 oxycodone		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2 unknown dates or duration	
<b>B. Adverse event or product problem</b>				2. Dose, frequency & route used #1 unknown dose, po #2 unknown dose, po			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 chronic back pain #2 chronic back pain		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) ( ) disability ( ) life-threatening ( ) congenital anomaly (X) hospitalization - initial or prolonged ( ) required intervention to prevent permanent impairment/damage ( ) other:				6. Lot # (if known) #1 Unknown #2 unknown		7. Exp. data (if known) #1 Unknown #2 unknown	
3. Date of event unknown (mo/day/yr)		4. Date of this report 02/06/98 (mo/day/yr)		9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
5. Describe event or problem  Case # 338 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. VALIUM® (unknown dose or duration)  Sect. C10: See attached case report form provided by [redacted]			
6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted]				<b>G. All manufacturers</b>			
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 ( ) consume:  (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) HEART ARREST      RESPIRATORY DIS MYOPATHY            KIDNEY FAILURE LIVER DAMAGE        EDEMA BRAIN INFARCT CEREBR     DEATH	
				9. Mfr. report number 0929634A			
				<b>E. Initial reporter</b>			
				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) Ur			





19-FEB-1998-0703



\*3031788-2-00\*

**TESS FATALITY: 1996**

**Case Number:** 338  
**Age:** 40 yrs  
**Substances:** Oxycodone  
acetaminophen/hydrocodone  
diazepam  
**Chronicity:** Acute on chronic  
**Route:** Ingestion  
**Reason:** Int Unknown  
**Pre-Hospital Arrest?** Yes

40 yo male with a history of chronic back pain on Vicodin, Oruvail, Norgesic, Ultram, Surmontil, Prilosec, Valium and Soma was in his normal state of health the night prior to admission except for increased somnolence. In the morning his wife found him unresponsive. The paramedics found him asystolic and apneic but resuscitated him with ACLS care. In the ED he was lavaged and given activated charcoal and a cathartic. He required vasopressors initially but these were quickly weaned off. Because of a positive response to Narcan he was started on a continuous Narcan infusion. His initial ABG showed pH 7.38, pCO2 91 mmHg, pO2 81 mmHg, BE -23 mmol/L and bicarb 13 mmol/L. His initial sodium 140 mmol/L, potassium 6.0 mmol/L, chloride 106 mmol/L, bicarb 15 mmol/L, BUN 27 mg/dL and creatinine 3.0 mg/dL. His EKG showed a small positive R wave in aVr, QRS 86 msec and Qtc 493 msec. His urine drug screen was positive for amphetamines, marijuana, opiates, benzodiazepines, trimipramine, oxycodone, and hydrocodone. His acetaminophen level was 5.0 ug/ml and salicylate level 3.9 mg/dL. Serum oxycodone level was 46 ng/ml (17-36) about 9 hours after arrival to the ED. Hospital course was complicated by fever and pulmonary infiltrates, rhabdomyolysis (CPK 20815 U/L), renal failure (BUN 125 mg/dL, creatinine 10.3 mg/dL) and liver dysfunction (AST 24130 U/L, LDH 28240 U/L, INR 1.91 and PTT 35.2). Repeat CT scan on hospital day 4 showed severe cerebral edema and several infarcts. There was no improvement in his mental status and on day 6 ventilatory support was discontinued and he died soon after.