



REC'D



McNeil Consumer Healthcare
Ft. Washington, PA 19034-2299

Mfr report #
UF/Dist report #
Approved by FDA on 11/15/93
FDA use only

Page ___ of ___

A. Patient information

1. Patient identifier 21137583 In confidence	2. Age at time of event: 35 yrs Date of birth: [redacted]	3. Sex (X) female () male	4. Weight unk lbs or kgs
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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified TYLENOL product #2 VICODIN®		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 6/22/00-6/25/00; 4 days #2 6/22/00-6/25/00; 4 days	
2. Dose, frequency & route used #1 unknown dose, po #2 40 over 2 days		4. Diagnosis for use (indication) #1 chronic abdominal pain #2 unknown	
5. Event abated after use stopped or dose reduced #1 () Yes (X) No () N/A #2 () Yes (X) No () N/A		7. Exp. date (if known) #1 Unknown #2 unknown	
6. Lot # (if known) #1 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) unknown			

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions) (check all that apply)	() disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:
2. Outcomes attributed to adverse event (check all that apply)	(X) death (mo/day/yr) 6/27/00 () life-threatening (X) hospitalization - initial or prolonged
3. Date of event (mo/day/yr) 6/25/00	4. Date of this report (mo/day/yr) 07/25/00

5. Describe event or problem

Pharmacist report from Drug Information Service rec'd via fax from affiliate of OVERDOSE & DEATH (died) allegedly associated w/ an unspecified TYLENOL® product & VICODIN® in a 35 yo F. According to report, pt was found unresponsive at home & taken to hosp. Spouse reported that pt had taken 40 VICODIN over past 2 days. Pt was acidotic (ACIDOSIS) & hypotensive (HYPOTENSION). At an unspecified interval after ingestion, APAP level=137, AST greater than 9000, ALT greater than 4000, glucose less than 20 (HYPOGLYCEMIA), & (+) opiate screen. Pt was also found to be bleeding (HEMORRHAGE) from Foley catheter site, NG tube, & endotracheal tube site. Tx w/HUCOMYST® was initiated. Pt was transferred to a second hosp & admitted to Critical Care Medical Unit for further management. On 6/26/00, APAP level=114, AST greater than 7000, ALT greater than 3000, INR=2.1, PT=21.5 (PROTHROMBIN INCREASED) & PTT=43.0. It was later determined that support would be replaced w/comfort care. On 6/27/00 at 1:20 pm, pt died due to irreparable HEPATIC FAILURE & (see sect B7)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	2. Phone number 215-273-7303
3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:	

JUL 28 2000 JUL 31 2000

4. Date received by manufacturer (mo/day/yr) 07/17/00	5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes
6. If IND, protocol #	8. Adverse event term(s) OVERDOSE DEATH ACIDOSIS HYPOTENSION HYPOGLYCEMIA HEMORRHAGE PROTHROMBIN INC LIVER FAILURE
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #	9. Mfr. report number 1400311A

6. Relevant tests/laboratory data, including dates
6/25/00 (first hosp): at unspec time APAP level=137, AST greater than 9000, ALT greater than 4000, glucose less than 20, (+) opiate screen; 6/26/00: APAP=114, AST greater than 7000, ALT greater than 3000, INR=2.1, (see sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
African American, no tobacco or alcohol use, (+) opiate use for past 3 years
(sect B6 cont) PT=21.5, PTT=43.0
(sect B5 cont) multi-organ failure related to overdose of ENOL & VICODIN. Specific information regarding the amount TYLENOL ingested was not provided.

E. Initial reporter

1. Name, address & phone # [redacted] Box [redacted] Drive [redacted]		2. Health professional? (X) Yes () No	3. Occupation Pharmacist	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.