

McNEIL CONSU
FORT WA
Page

Individual Safety Report
3 37713-2-00

A. Patient information

1. Patient identifier Case # 14 In confidence	2. Age at time of event: 34 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs
---	--	----------------------------------	-----------------------------------

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)
3. Date of event (mo/day/yr) 10/11/94	4. Date of this report (mo/day/yr) 02/11/98

- (x) death (12/5/94)
- () life-threatening
- (x) hospitalization - initial or prolonged
- () disability
- () congenital anomaly
- () required intervention to prevent permanent impairment/damage
- () other:

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 TYLENOL Analgesic Unknown	#1 10 and 16 TYLENOL, po	#1 unknown dates PTA
#2 DARVOCE [®]	#2 4-16 PTA	#2 unknown dates or duration
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	6. Event reappeared after reintroduction
#1 for a fall	#1 () Yes () No (X) N/A	#1 () Yes () No (X) N/A
#2 for a fall	#2 () Yes () No (X) N/A	#2 () Yes () No (X) N/A
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 Unknown	#1 Unknown	#1 () Yes () No (X) N/A
#2 unknown	#2 unknown	#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	

G. All manufacturers

1. Contact office - name/address (& phone # 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) 12/31/97	3. Report source (check all that apply)
5. (A) NDA # 17-552	() foreign
6. If IND, protocol #	() study
7. Type of report (check all that apply)	() literature
() 5-day (X) 15-day	() consumer
() 10-day () periodic	() health professional
(X) Initial () follow-up #	() user facility
8. Mfr. report number 0932159A	() company representative
9. OTC product (X) Yes	() distributor
10. Adverse event term(s)	(X) other: attorney

FEB 27 1998

Reports of 19 cases compiled by attorney & sent to FDA; Agency forwarded these reports to McNeil upon request to Docket No. 77N-094W, Ref. 94, Vol. 6 of 7. Of the 19 cases, 11 were previously submitted to FDA by McNeil (Mfr. # 0158783A, 0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223a, 0505252A, 0599479A, 0673820A). Case document #14 of 34 YO F w/ hx of moderate alcohol consumption who sustained a fall on 10/8 & consumed between 10 & 16 TYLENOL & 4-16 DARVOCE[®] PTA. On 10/11, pt had LIVER FUNCTION TESTS ABNORMAL. Pt went to ER w/fever & chills. Pt was anuric, somnolent & required intubation 48hrs later. On 3rd day, pt w/worsening hepatic coma. On 10/19, liver tx performed. Pt developed liver dysfunction, KIDNEY FAILURE, ENCEPHALOPATHY, QUADRIPLEGIA w/ bowel & bladder incontinence & myoclonic status epilepticus (GRAND MAL CONVULSIONS). On 12/5/94, pt died (DEATH). Surgical pathology report on native liver lists final dx: extensive centrilobular necrosis (LIVER NECROSIS) w/presence of Mallory bodies c/w TYLENOL toxicity & alcohol intake.

6. Relevant tests/laboratory data, including dates
On presentation: SGOT=1145, bili=7; 12/5/94: NH3 level went from 500 to 1000, PT went from 12 to 21 sec; CT documented severe cerebral edema & a subarachnoid bleed; Cerebral blood scintigraphy consistent w/brain death (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
three week history of 17 pound weight loss, nausea & vomiting; previous history of moderate alcohol consumption

Sect B6 cont'd: Surgical pathology report on native liver; final diagnosis (10/19/94): extensive centrilobular necrosis w/presence of Mallory bodies, fatty change & cholestasis

E. Initial reporter

1. Name, address & phone #	2. Health professional? () Yes (X) No	3. Occupation attorney	4. Initial reporter also sent report to FDA (X) Yes () No () Unk
----------------------------	--	---------------------------	--



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.