



REC'D

2000



Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ___ of ___

Approved by FDA on 11/18/93

Mfr report #
UF/Dist report #
FDA use only

A. Patient information

1. Patient Identifier Case 3 In confidence	2. Age at time of event: 15 yrs Date of birth:	3. Sex (X) female () male	4. Weight lbs or 75 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)	
() death (mo/day/yr)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	(X) required intervention to prevent permanent impairment/damage
() other:	
3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 01/24/00

5. Describe event or problem

Lit report (Pediatr Rev 1999;20(9):309-313) of OVERDOSE in a 15 yo F. According to report, pt ingested approx 15 Extra Strength TYLENOL® Tablets (7.5g) and approx 1.5 oz of an unspecified hydrocodone cough suppressant "to sleep". Pt presented to ER w/ 1 day h/o 11 episodes of bilious VOMITING w/abd pain. On PE, pt appeared alert w/tender upper abdomen. No bowel sounds were audible. Liver edge was palpable 2 cm below the costal margin. At an unspecified time WBC=3.2 x (9)/L (LEUKOPENIA). Hgb, plts, liver enzymes, bili & pancreatic enzymes were nl. Abd radiograph was c/w ILEUS. Pt was admitted to hosp for hydration & monitoring. Pt tx w/ ranitidine. The next day, 30 ml of brown, guaiac (+) fluid containing small, BRB clots drained from NG tube. Endoscopy revealed esophagitis, duodenitis & gastric erosions but no active bleeding. Repeat blood tests showed: ALT=2697, AST=251 (LIVER FUNCTION TESTS ABNORMAL), Tbili=18.7 (BILIRUBINEMIA), amylase=181, lipase= 515(ENZYMATIC ABNORMALITY) & PT=14.1 (PROTHROMBIN INCREASED). No ASA or APAP (See Sect B7)

6. Relevant tests/laboratory data, including dates

On exam: guaiac-negative stool, WBC=3.2x10(9)/L, urine pregnancy test=(-), abdominal radiograph c/w ileus, CT of abd w/ contrast nl; at unspecified time: ALT=2697 U/L, AST=251 U/L, Tbili=18.7umol/L, amylase= 181 U/L, lipase=515 U/L, PT=14.1

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

pt finishing regular menstrual cycle; pt sexually active & uses condoms inconsistently (Sect B5 cont) detectable in blood. The next day, pt admitted taking the described medications @ 1:30 AM on day of admission. Pt rec'd NAC via tube q6hrs for 13 doses. Liver enzymes peaked on 3rd nosp day & normalized by 25th day. Pancreatic (See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 Extra Strength TYLENOL Tablets	
#2 unspecified hydrocodone cough suppressant	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 approx 7.5 g, 1:30am, po	#1 unknown date; once
#2 approx 1.5 oz, 1:30am, po	#2 unknown date; once
4. Diagnosis for use (indication)	
#1 "to sleep"	
#2 "to sleep"	
5. Event abated after use stopped or dose reduced	
#1 () Yes () No (X) N/A	
6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2 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 (Sect B7 cont) enzymes fluctuated in high range for more than 4 weeks & pt req'd PPN for 12 days. Pt was evaluated by psychiatry, & once cleared medically was transferred to inpatient psych unit.	

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-273-7303
3. Report source (check all that apply)	
() foreign	
() study	
(X) literature	
() consumer	
(X) health professional	
() user facility	
() company representative	
() distributor	
() other:	
4. Date received by manufacturer (mo/day/yr)	5. (A) NDA #
01/24/00	19-872
6. If IND, protocol #	IND #
	PLA #
	pre-1938 () Yes
7. Type of report (check all that apply)	OTC product (X) Yes
() 5-day (X) 15-day	
() 10-day () periodic	
(X) Initial () follow-up #	
8. Adverse event term(s)	
OVERDOSE	VOMITING
LEUKOPENIA	ILEUS
LIVER FUNC ABNO	BILIRUBINEMIA
ENZYME ABNORM	PROTHROMBIN INC
9. Mfr. report number	
1303197A	

FEB 04 2000

E. Initial reporter

1. Name, address & phone #		
[REDACTED]		
[REDACTED]		
[REDACTED]		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes () No	physician	() 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.

Facsimile Form 3500A