

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



McNEIL CONSUMER PRO  
FORT WASHINGTON



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<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient Identifier unknown In confidence	2. Age at time of event: 17 yrs Data of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2 TYLENOL PM		2. Dose, frequency & route used #1 unknown dose, occasionally #2 unknown dose, po	
<b>B. Adverse event or product problem</b>				3. Therapy dates (if unknown, give duration) from/to for best estimate #1 unknown #2 unknown		5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnose for use (indication) #1 headache, muscle cramps, backache #2 help him sleep		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A	
2. Outcome attributed to adverse event (check all that apply) ( ) death (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) 6/30/98		4. Date of this report (mo/day/yr) 08/10/98		9. NDC # - for product problems only (if known)			
5. Describe event or problem Medical toxicologist report of ABNORMAL ENZYME (elevated lipase), high LFT's, KIDNEY FAILURE (renal failure), MYOPATHY (rhabdomyolysis) & THROMBOCYTOPENIA in a 17 yo male patient w/hx of prior brain injury following MVA 1 year ago. Patient presented to ER hypotensive (HYPOTENSION); CPR was performed & patient admitted to hospital 6/30/98 for LIVER FAILURE & renal failure. Patient reportedly used TYLENOL PM help him sleep, occasional TYLENOL for aches & pains; & tramadol for pain for at least 1 month. Urinalysis: acetaminophen level was 6 ug/ml 12 hours after his last being seen PTA. Initial LFT's & elevated lipase declined as did the evidence for thrombocytopenia & rhabdomyolysis. As of 7/12/98, LFT's in 200-300 range; creatinine elevated at 10 & patient undergoing dialysis daily. Physician attributes event possibly to tramadol. Addl info rec'd 8/6/98: Physician's note indicates the CK level was greater than 20,000 (CREATINE PHOSPHOKINASE INCREASED). Pt now in rehab unit. 7/29/98: LFT's 100-150. RFT's now NML.				10. Concomitant medical products and therapy dates (exclude treatment of event) Sect C.#3: tramadol, pain, unknown dose, po, for at least 1 month			
6. Relevant tests/laboratory data, including dates in hosp: urine tox (+)acetaminophen, diphenhydramine, & tramadol; plasma acetaminophen: 6 ug/ml 12 hrs after being seen PTA initial LFT's elevated; 7/10/98; LFT's- 400 range; 7/12/98; LFT's 200-300; creatinine=10; (see Sect. B7)				<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.) history of prior brain injury from MVA 1 year ago, chronic headaches, leg cramps, occasional insomnia.  Sect. B6 cont.: CK greater than 20,000; 7/29/98: LFT's 100-150; RFT's now normal				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) 08/06/98		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer (X) health professional ( ) user facility ( ) company representative ( ) distributor ( ) other:	
				6. If IND, protocol #		(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 ( ) initial (X) follow-up # 1		8. Adverse event term(s) ENZYME ABNORM KIDNEY FAILURE MYOPATHY THROMBOCYTOPENIA HYPOTENSION LIVER FAILURE CREATINE PK INC	
				9. Mfr. report number 1003483A			
				<b>E. Initial reporter</b>			
				1. Name, address & phone # [redacted] MD [redacted] Center PO BOX [redacted]		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk	
				2. Health professional? (X) Yes ( ) No		3. Occupation toxicologist	



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

AUG 17 1998