

Individual Safety Report



3484748-7-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ___ of ___

Approved by FDA on 11/15/03

Mfr report #
UP/Dist report #
FDA use only

A. Patient information

1. Patient Identifier In confidence	2. Age at time of event: or 50 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs
--	---	----------------------------------	-----------------------------------

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 unspecified TYLENOL product		#1 unknown dates; 2-3 wks	
#2 TAMIFLU (osteltamivir) 75 mg		#2 2/9/00-2/13/00	
2. Dose, frequency & route used		4. Diagnosis for use (indication)	
#1 approx 3-4 tabs/day, po		#1 influenza	
#2 unknown dose, po		#2 unknown	
6. Lot # (if known)		7. Exp. date (if known)	
#1 unknown		#1 unknown	
#2 unknown		#2 unknown	
9. NDC # - for product problems only (if known)		5. Event abated after use stopped or dose reduced	
		#1 (X) Yes () No () N/A	
		#2 () Yes () No (X) N/A	
		8. Event reappeared after reintroduction	
		#1 () Yes () No (X) N/A	
		#2 () Yes () No (X) N/A	
10. Concomitant medical products and therapy dates (exclude treatment of event) unk (Sect B7 cont): elevation of liver enzymes. Addl info rec'd 3/28/00:MD's note indicates pt was taking TYLENOL for influenza. Final dx listed in medical records: 1. APAP hepatitis, 2. acute renal insufficiency, & 3. dehydration.			

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	() disability
2. Outcomes attributed to adverse event (check all that apply)	() congenital anomaly
() death (m/d/y)	() required intervention to prevent permanent impairment/damage
() life-threatening	(X) other: recovered
(X) hospitalization - initial or prolonged	

3. Date of event (m/d/y)	4. Date of this report (m/d/y)
unknown	03/29/00

5. Describe event or problem

MD report rec'd via other manufacturer of elevated liver enzymes (LIVER FUNCTION TESTS ABNORMAL), renal insufficiency (KIDNEY FUNCTION ABNORMAL), HEPATITIS, CONFUSION, & DEHYDRATION in pt taking TYLENOL. Addl info rec'd 3/10/00: MedMatch (Mfr. Rep#229992) from Roche indicates 50 yo F using TAMIFLU & TYLENOL. Pt had sx of NAUSEA, VOMITING, DIARRHEA, & low grade temp (FEVER) on 2/1/00. 2/9/00 pt started TAMIFLU. 2/12/00 pt developed confusion, disorientation, visual HALLUCINATIONS & anorexia. Husband reports pt took APAP approx 3-4 tabs/d. 2/13/00 pt went to ER & prescribed promethazine. 2/15/00 pt transferred to other hosp & started on IV rehydration. APAP level=11. Pt had scattered purpuric lesions on bil extensor surfaces of arms. CT= scattered subcortical & periventricular areas of decreased attenuation most consistent w/small vessel dx. Abd US=somewhat coarse hepatic texture consistent w/ either fatty infiltration or fibrosis & mildly echogenic kidneys consistent w/hx of chronic renal impairment. Neg hepatitis panel. 2/18/00 pt's labs approaching (See Sect B6)

6. Relevant tests/laboratory data, including dates

2/15/00 HCT=27.3, PLT=125,000, SGOT=4134, SGPT=1672, BUN=54, Scr=6.8, Alk Phos=186, pH=7.31, pCO2=34, pO2=109; 2/18/00 Alk Phos=150, Alb=1.8, APAP level =11 (Sect B5 cont): nl. SGPT=308, SGOT=204, alb=1.8, Alk Phos=150. Pt d/c from hospital (See Sect B7)

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

CRI, HTN, hypothyroidism, hyperlipidemia, hysterectomy 8 wks PTA for menorrhagia w/resultant IDA; NKDA (Sect B6 cont): It was reported that pt's elevated liver enzymes & acute renal failure were secondary to APAP hepatitis & severe dehydration. Physician's felt that chronic low level use of APAP could produce significant (See Sect C10)

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 19036	215-273-7303
4. Date received by manufacturer (m/d/y)	3. Report source (check all that apply)
03/28/00	() foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:
5. (A) NDA #	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 () initial (X) follow-up # 1	8. Adverse event term(s)
9. Mfr. report number	LIVER FUNC ABNO KIDNEY FUNC ABN HEPATITIS CONFUSION DEHYDRATION NAUSEA VOMIT DI FEVER HALLUCINATIONS
1325843A	

E. Initial reporter

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