



Mfr report # 7397510
UF/Dist report #
FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient Information						
1. Patient Identifier in confidence	2. Age at time of event: 39 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight			
B. Adverse event or product problem						
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)						
2. Outcomes attributed to adverse event (check all that apply)						
<input type="checkbox"/> death (mo/day/yr)		<input type="checkbox"/> disability		<input type="checkbox"/> congenital anomaly		
<input type="checkbox"/> life-threatening		<input type="checkbox"/> required intervention to prevent permanent impairment/damage		<input type="checkbox"/> other: Improved		
<input type="checkbox"/> hospitalization -initial or prolonged						
3. Date of event (mo/day/yr) 12/03/98	4. Date of this report (mo/day/yr) 12/07/98					
5. Describe event or problem						
Report of increased ALT, AST and direct bilirubin coincident with ZYFLO therapy. In approximately 6/97, the patient began ZYFLO therapy. On 12/3/98, an increased ALT level was noted on routine labwork. On 12/8/98, repeat labwork revealed an increased AST and direct bilirubin, the ALT had slightly decreased. The MD stated that the patient had taken 1 gm of TYLENOL three times daily from 11/28/98 to 12/2/98. The patient continues on ZYFLO therapy and the event continues. The MD believes the event is related to ZYFLO therapy but the TYLENOL may have contributed to the events as well. Additional information received 12/22/98: liver function tests were redrawn 12/14/98. The ALT was increased to 248. The patient had not taken any TYLENOL since 12/2/98. ZYFLO therapy was discontinued on 12/14/98. The patient is asymptomatic. On 12/28/98, labwork revealed a decreased ALT. The patient continues to improve. The MD believes the events are related to ZYFLO therapy.						
- Indicates estimated values						
6. Relevant tests/laboratory data, including dates						
	12/3/98	12/8	12/14	12/28	1/11/99	Normals
ALT	221	200	248	216	97	15-61
AST		87				
Direct Bill		0.3				0-0.2
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)						
The patient is allergic to ASPIRIN and SULFA. History includes nasal polyps and a polypectomy. No history of hepatitis, cirrhosis, gall bladder or hepatic disease. The MD believes the patient may drink, but very infrequently, only at social occasions.						

C. Suspect medication(s)			
1. Name (give labeled strength & mfr./labeler, if known)			
#1 Abbott - Zylfo			
#2 Tylenol			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 600.000 MG PO QID		#1 06/Unk/97--12/14/98	
#2 1.000 GM PO TID		#2 11/28/98-12/02/98	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Asthma		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 Unknown		#1 Unknown	
#2		#2	
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
slc-bid	Unknown - Present		
Vancoril	Unknown - Present		
Pionase	Unknown - Present		
Tylenol	2880V98-02HMC98		
	1.00M		

G. All manufacturers(s)		
1. Contact office - name/address (& mailing site for devices)		2. Phone
Jeanne Fox D-491 AP6B Abbott Laboratories 100 Abbott Park Road Abbott Park, Ill 60064-3500		(847)937-5533
4. Date received by manufacturer (mo/day/yr) 12/07/98		3. Report source (check all that apply)
6. If IND, protocol #		<input type="checkbox"/> foreign
7. Type of report (check all that apply)		<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day		<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic		<input type="checkbox"/> consumer
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #		<input checked="" type="checkbox"/> health professional
9. Mfr report number 7397510		<input type="checkbox"/> user facility
		<input type="checkbox"/> company representative
		<input type="checkbox"/> distributor
		<input type="checkbox"/> other
8. Adverse event term(s) SGPT INC SGOT INC BILIRUBINEM		

E. Initial reporter			
1. Name, address & phone #			
[Redacted], MD			
[Redacted] Drive			
[Redacted]			
[Redacted]			
[Redacted]			
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2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	