

Individual Safety Report



3214648-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting
health professionals of adverse
events and product problems

CDER

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **98678**

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A. Patient information

1. Patient identifier 3857 In confidence	2. Age at time of event: 42 or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. Adverse event and/or 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"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) **12/27/96**

4. Date of this report (mo/day/yr) **2/28/99**

5. Describe event or problem

3857- OD, APAP
42yo M admitted to Misericordia lethargic and icteric following an unknown amount of acetaminophen ingestion for presumed sickle cell crisis. Level returned <10 with AST >8000, ALT 1950, LDH 9040, tbili 11.5, GGT 238, ammonia 140. PMH includes hepatitis B and EtOH abuse in past. Patient was transferred to HUP for liver transplant evaluation. MS improved and LFTs improved, but transplant evaluation halted when noted to be actively using alcohol. Left AMA 1/6 before transfer back OSH to primary physician.

6. Relevant tests/laboratory data, including dates

REC'D.
MAR 05 1999
MEDWATCH CTU

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

HIV, Hep B



CTU 98678

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)		3. Therapy dates (if unknown, give duration) (mo/yo (or best estimate))	
#1 Acetaminophen		#1 12/27/96	
#2 _____		#2 _____	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 unknown		#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	
4. Diagnosis for use (indication)		6. Lot # (if known)	
#1 sickle cell crisis		#1 _____	
#2 _____		#2 _____	
7. Exp. date (if known)		8. Event reappeared after reintroduction	
#1 _____		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 _____		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # (for product problems only)			
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10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name		4. Operator of device	
2. Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____	
3. Manufacturer name & address		5. Expiration date (mo/day/yr)	
DSS MAR - 8 1999		6. If implanted, give date (mo/day/yr)	
6. model # _____		7. If explanted, give date (mo/day/yr)	
catalog # ADVERSE EVENT REPORTING SYSTEM		8. If explanted, give date (mo/day/yr)	
serial # _____		9. Device available for evaluation? (Do not send to FDA)	
lot # _____		<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
other # _____		10. Concomitant medical products and therapy dates (exclude treatment of event)	
9. Device available for evaluation? (Do not send to FDA)		_____	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)		_____	

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
Pharm.D. - _____ _____ _____			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Also reported to	
		<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178