



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

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Form Approved: OMB No. 0916-0291 Expires: 11/30/00
See OMB statement on reverse

FDA Use Only

Triage unit sequence #	129811
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A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 23 Years or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 150 lbs or kgs
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In confidence

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 (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event: 01/23/2000 (mm/dd/yyyy)

4. Date of this report: 09/28/2000 (mm/dd/yyyy)

5. Describe event or problem

[redacted] presented to an outside hospital with malaise, fatigue and projectile vomiting on 1/22/00. She had consumed 100 tablets of Tylenol over a period of 4 days for a toothache. She was in her 29th week of pregnancy with fetal demise -vaginally delivered 1/23/00-. She was transferred to this hospital -1/24/00- and noted to have conjunctival hemorrhage, slight jaundice, but no cyanosis. She was treated for renal insufficiency and liver failure. She was referred to the dental clinic for extraction of teeth #17 and #31. The patient improved with supportive treatment and acetylcysteine and was discharged 1/27/00.

6. Relevant tests/laboratory data, including dates

Initial Labs: AST 1871, ALT 3178, PT 19.1, INR 1.7, PTT 36.5, ALK Phos 286, bilirubin 1.8, GGTP 103, Acetaminophen level 8.5 mg/mL, BUN 28, Cr 1.5, Hct 33.8, WBC 28.8, Plts 242. Discharge Labs: AST 75, ALT 708, PT 12.6, PTT 28.7, bilirubin 1.9, GGTP 193, BUN 11, Cr 0.7, WBC 12.3, Plts 248

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

She had a previous pregnancy which was complicated with chorioamnionitis and required a cesarean section. No known drug allergies. +- smoking history. --- drug or alcohol use. No family history of liver disease.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 acetaminophen / /	
#2 / /	
2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 500 mg / 25 tabs/d / Oral	#1 01/18/2000 - 01/21/2000
#2 / /	#2 -
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced
#1 toothache - self diagnosis	#1 <input type="checkbox"/> yes <input checked="" 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	#1
#2	#2
9. NDC # (for product problems only)	8. Event reappeared after reintroduction
-	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event)	
none	

D. Suspect medical device

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

E. Reporter (see confidentiality section on back)

1. Name	phone #	
[redacted]	[redacted]	
Drug Information Center [redacted] St [redacted] United States [redacted]		
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer <input checked="" 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, Room 5078
Rockville, MD 20857
or FAX to: 800-FDA-0178

FDA Form 3500

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

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