



3530359-9-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CDER

FDA Use Only

Triage unit sequence #	125763
CDER	

A. Patient information

1. Patient Identifier 30922499 <small>In confidence</small>	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input 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 (m/m/d/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input checked="" 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 (m/m/d/yyyy) 06/27/2000

4. Date of this report (m/m/d/yyyy) 07/17/2000

5. Describe event or problem

Patient admitted to Acute Care Medical GI unit 6/27 with abnormal liver function tests. Acetaminophen level was 31.6. On 6/30 ICP monitor placed, because intracranial pressure was elevated related to hepatic failure due to Tylenol ingestion. Patient was discharged 7/13/2000.

6. Relevant tests/laboratory data, including dates

6/28/2000: Acetaminophen level 31.6, pH 7.19, INR 2.3, AST 6002, ALT 6736, ALK 147, albumin 2.6

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

DSS
JUL 18 2000

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Tylenol / unknown / McNeil Consumer Healthcare	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 06/27/2000 - 06/27/2000
2. Dose/Frequency/Route used #1 unkno / / #2 / /	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1 unknown #2	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
6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2
9. NDC # (for product problems only)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other:

5. Expiration date (m/m/d/yyyy)

6. model # JUL 17 2000

7. If implanted, give date (m/m/d/yyyy)

8. If explanted, give date (m/m/d/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on (m/m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone [redacted]

[redacted] Drive [redacted] Box [redacted]

[redacted] United States

2. Health professional?
 yes no

3. Occupation
Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20857-0347
or FAX to: 1-800-FDA-0178

FDA Form 3500
CTV125763

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