



3731023-3-00-01

VOLUNTARY reporting
by health professionals of adverse
events and product problems

FDA Use Only

Triage unit sequence: 144517

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

A. Patient information

Patient identifier	2. Age at time of event: or <u>21 years</u> Date of birth:	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight <u>142</u> lbs or <u>78.6</u> 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	<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 checked="" type="checkbox"/> other:

3 Date of event: 4/9/2000

4 Date of this report:

5. Describe event or problem
Hepatitis,
Acetaminophen induced. ?
(Marked jaundice)

6. Relevant tests/laboratory data, including dates
Abnormal LFTs

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
(Voltaren Allergy)
Hx of analgesic abuse Voltaren, Advil
Tylenol

C. Suspect medication(s)

1. Name (give labeled strength & mfr./labeler, if known)

#1 Acetaminophen

#2

2. Dose, frequency & route used

#1 FOR 3 days

#2

3. Therapy dates (if unknown, give duration)

#1

#2

4. Diagnosis for use (indication)

#1 Analgesic

#2 Antipyretic

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1

#2

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

**RECEIVED
MAY 30 2001
MEDWATCH CTU**

4. Operator of device

health professional
 lay user/patient
 other:

5. Expiration date

6. model #

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer or

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

DSS

31 2001

2. Health professional? yes no

3. Occupation PHARMACIST

4. Also reported to

manufacturer
 use 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 20852-9787

or FAX to:
1-800-FDA-0178