



OLUNTARY reporting  
lth professionals of adverse  
its and product problems

CDER

Form Approved: OMB No. 0910-0291 Expires: 12/31/96  
See OMB statement on reverse

FDA Use Only  
Triage unit  
sequence # 127812

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

**A. Patient information**

1. Patient identifier <u>4775</u> In confidence	2. Age at time of event: or Date of birth: <u>[redacted]</u>	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or <u>80</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 (m/d/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening (m/d/yyyy)	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyyy) 3/5/00

4. Date of this report (m/d/yyyy) 3/15/00

5. Describe event or problem

adr_id	adr_desc
<u>4775</u>	28 YOF bx from [redacted] on 3/7/00 with acute liver failure secondary to Acetaminophen toxicity. On 3/4, pt had persistent HA and used Tylenol PM - 4 tablets. Pt also ingested and drank approx 32 oz beer and a few mixed drinks. On 3/5 AM, pt ingested a total of 10-14 tabs of Tylenol PM (5-7GM APAP) over a 12 hour period. Pt found in PM by mom and was extremely somnolent. In ED, APAP level 139, INR 17.9, slight inc LFTs. RX with Charcoal and Acetylcysteine. Tbili at 6.8 on transfer with elev LFTs. Pt worsened and by 3/9, pt to OR for emergent liver transplant.

6. Relevant tests/laboratory data, including dates

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

PMH: asthma, congenital nystagmus, congenital cataracts, headaches, legally blind, tubal ligation

alcohol use 4-6 drinks / week

NKDA

CT 127812

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

or FAX to: 1-800-FDA-0178

**C. Suspect medication(s)**

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

#1 Acetaminophen 500mg Tylenol PM

#2 Diphenhydramine 25mg

2. Dose, frequency & route used

#1 5-7 grams x 1

#2 250-350mg x 1

3. Therapy dates (if unknown, give duration) (m/d/yyyy) (or best estimate)

#1 3/4/00-3/5/00 over a 12hr period

#2 3/4/00-3/5/00

4. Diagnosis for use (indication)

#1 Headache

#2 Headache

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)

Albuterol Inhaler

**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: \_\_\_\_\_

RECEIVED

5. Expiration date (m/d/yyyy)

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6. model # \_\_\_\_\_

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

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

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

yes  no  returned to manufacturer on \_\_\_\_\_ (m/d/yyyy)

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

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone # \_\_\_\_\_ PharmD

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.



127812

LAB DATA (if needed)

	3/7	3/8	3/9	3/10	3/11	3/12	3/13	3/14	3/15	3/16	3/17								
Tbili	3.5 4.9	6.0	6.8 6.0	2.4	1.4	1.2	-	1.5	1.5	1.1	1.2								
AST	15150 21222	1467	3286 5002	3936	2071	3059	402	261	173	135	141								
ALT	1250 1576	1481	617 3036	4888	4263	7334	2371	1624	997	869	755								
Alk	183	231	114 197	246	319	304	255	260	248	253	298								
LOT	55902		11093	2230	3623														

REPORTER: Please TURN to other side

CGT 33 59 65  
49 60

CONFIDENTIAL: FOR PEER REVIEW ONLY/QUALITY ASSURANCE

Ammonia 68 226  
183  
PT 55.1 - 20.4/2.9 16.9/2 15.7/1.7 14.4/1.3 13.6/1.3  
PT 55.1 - 31.6 28.2 22.6 21.1

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127812