



VOLUNTARY reporting
alth professionals of adverse
nts and product problems

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

FDA Use Only
Triage unit sequence # **133627**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page **1** of **1**

COBR

A. Patient information

1. Patient identifier **4910**
In confidence

2. Age at time of event: **25**
or Date of birth: **12/28/74**

3. Sex female male

4. Weight **135** lbs or **73.5** kgs

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)

death (m/day/yr)

life-threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other:

3. Date of event (m/day/yr) **6/13/00**

4. Date of this report (m/day/yr) **6/21/00**

5. Describe event or problem

25 YOM with HIV and PCP on Stavudine/Lamivudine/Nevirapine from 1/00 to 5/00. Pt also had intermittent abd pain over past year which worsened 3/00 with NV/F, fatigue and myalgias. Pt adm 4/00, all w/u negative. Between April and June pt was taking 10-16 tabs APAP per day for abdominal pain. Pt adm 6/13 to OSH with jaundice. Liver bx with hepatocellular necrosis. Pt tx here 6/18. Tbil 16 on admission. Differential diag including APAP toxicity.

6. Relevant tests/laboratory data, including dates

Liver biopsy revealed foci hepatocellular necrosis, suggesting possible result of acute viral infection medication effect or toxins.

Date	ALT	AST	AST	Tbil	Tox Acetaminophen
6/19	342	325	1616	16	6/19 ⊖
6/20	229	287	622	26	
6/21	116	297	245	26.6	

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

HIV/AIDS /

Allergy: Sulfu

CTU 133627

C. Suspect medication(s)

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

#1 **Tylenol (Acetaminophen)**

#2

2. Dose, frequency & route used **70**

#1 **10-16 tabs/dg**

#2

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

#1 **4/00 - 6/00**

#2

4. Diagnosis for use (indication)

#1 **Abdominal pain (OTC use)**

#2

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)

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

Zenit / Epiriv / Viramune

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/day/yr)

6. model #

catalog #

serial #

lot #

other #

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

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

yes no returned to manufacturer on (m/day/yr)

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

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional occupation

yes no **Pharmacist**

3. Also reported to

manufacturer

user facility

distributor

4. 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