



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr. report # \_\_\_\_\_  
U/F Dist report # \_\_\_\_\_  
FDA Use Only

**Patient information**

1. Patient Identifier: [REDACTED]  
2. Age at time of event: **66 Y**  
3. Sex:  female  male  
4. Weight: **79** lbs / **35** kgs  
Date of Birth: [REDACTED]

**B. Adverse event or product problem**

Adverse event and/or  Product Problem (e.g. defects/malfunctions)

2. Outcome attributed to adverse event (check all that apply):  
 Death  
 Life-Threatening (mo/day/yr)  
 hospitalization - initial or prolonged  
 Disability  
 Congenital Anomaly  
 required intervention to prevent permanent impairment/damage  
 Other

3. Date of Event (mo/day/yr): **01/25/1999**  
4. Date of this report (mo/day/yr): **02/22/1999**

5. Describe event or problem:  
**A 66-YEAR-OLD MALE PATIENT TOOK 10 MG OF CLARITIN ON 24JAN1999, FROM HIS DAUGHTER'S PRESCRIPTION, FOR A HEADACHE. ON 25JAN, THE PATIENT WAS UNABLE TO URINATE. HE WAS SEEN BY A UROLOGIST ON 26JAN. THE UROLOGIST FELT THE ACUTE URINARY RETENTION WAS SECONDARY TO THE CLARITIN AND A HISTORY OF BENIGN PROSTATIC HYPERPLASIA. THE PATIENT WAS GIVEN SOME SAMPLES OF FLOMAX (0.4 MG DAILY) FOR THE BENIGN PROSTATIC HYPERPLASIA AND PHENERGAN (PROMETHAZINE) 12.5 MG PO PRN WAS PRESCRIBED FOR NAUSEA. CLARITIN WAS DISCONTINUED AFTER RECEIVING ONLY ONE DOSE. ON 26JAN, THE PATIENT TOOK HIS FIRST FLOMAX CAPSULE. BETWEEN 27JAN AND 28JAN, HE COMPLAINED OF NAUSEA, BITTING, SHAKING CHILLS, AND A LOW GRADE TEMPERATURE. HE TOOK PHENERGAN, MILK OF MAGNESIA AND EIGHT EXTRA STRENGTH TYLENOL (ACETAMINOPHEN; EXACT DATES UNKNOWN). FLOMAX WAS DISCONTINUED ON 28JAN, AFTER THREE DOSES, BECAUSE OF THE PATIENT'S INABILITY TO KEEP ANYTHING DOWN. BETWEEN 29JAN AND 31JAN, THE PATIENT'S FAMILY NOTICED THE PATIENT WAS JAUNDICED. ON 1FEB, THE PATIENT SAW HIS PRIMARY CARE PHYSICIAN, WHO CONFIRMED THE JAUNDICE AND DARK URINE. THE PATIENT HAD NO RIGHT UPPER QUADRANT TENDERNESS, ITCHING OR LIGHTENED STOOLS. HEPATITIS A AND B SEROLOGIES WERE NEGATIVE. IT WAS REPORTED THAT AN UNSPECIFIED TEST WAS PERFORMED FOR HEPATITIS C, WHICH**  
 (CONTINUED)

6. Relevant tests/laboratory data, including dates

|          | 1FEB1999 | 5FEB  | 6FEB  | 7FEB |
|----------|----------|-------|-------|------|
| WBC      | 12000    | 17680 | 16530 | --   |
| EOS      | 17%      | --    | --    | --   |
| HGB      | WNL      | --    | --    | --   |
| HCT      | WNL      | --    | --    | --   |
| T.BILI   | 10.9     | 5.8   | 5.5   | 4.8  |
| ALK PHOS | 236      | 210   | 195   | 201  |
| AST      | 884      | 335   | 308   | 281  |
| ALT      | 1552     | 748   | 621   | 563  |

(CONTINUED)

7. Other relevant history, including preexisting medical conditions, (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
**HISTORY OF ANXIETY, DEPRESSION, IMPAIRED VISION, DEGENERATIVE ARTHRITIS, AND BENIGN PROSTATIC HYPERPLASIA. ALLERGIC TO PENICILLIN. NO KNOWN HISTORY OF TRANSFUSIONS, ALCOHOL USE, TRAVEL, DRUG USE, NEEDLE EXPOSURE OR RECENT SHELLFISH INGESTION. NO KNOWN HISTORY OF HEPATITIS C EXPOSURE. THE PHARMACIST REPORTED NO KNOWN HISTORY OF JAUNDICE. THE PHARMACIST WAS UNAWARE OF A HISTORY OF CHOLELITHIASIS OR GALL**  
 (CONTINUED)

**C. Suspect medication(s)**

1. Name (give labeled strength, mfr/labeler, if known)  
 #1 **FLOMAX (TAMSULOSIN HCL) CAPSULES**  
 #2 **ATIVAN**  
 (CONT)

2. Dose, frequency, route used  
 #1 **0.4 MG DAILY ORAL**  
 #2 **4 MG**

3. Therapy dates (if unknown, give duration) from/to (or best estimate)  
 #1 **01/26/1999-01/28/1999**  
 #2 **02/04/1999-02/04/1999**

4. Diagnosis for Use (Indication)  
 #1 **BENIGN PROSTATIC HYPERPLASIA**  
 #2 **UNKNOWN**

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 (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)  
**PREVACID FROM 02/05/1999 TO 02/05/1999 ; XANAX**

**G. All manufacturers**

1. Contact office-name / address (mfring site for devices)  
**SCHERING-PLOUGH CORPORATION  
 2000 GALLOPING HILL ROAD  
 KENILWORTH, NJ 07033**

2. Phone Number  
**(973)921-7435**

3. Report Source (check all that apply)  
 foreign  health professional  
 study  User facility  
 literature  Company representative  
 Consumer  distributor  
 Other:  
**BOEHRINGER**

4. Date received by manufacturer (mo/day/yr)  
**02/17/1999**

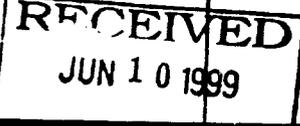
5. (A) NDA # **19-658**  
 IND # \_\_\_\_\_  
 PLA # \_\_\_\_\_  
 pre-1938  yes  
 OTC product  yes

6. If IND, protocol # \_\_\_\_\_

7. Type of report (check all that apply)  
 5-day  15-day  
 10-day  periodic  
 Initial  follow-up# \_\_\_\_\_

8. Adverse Event Term(s)  
**HEPATITIS  
 CONFUSION  
 URINARY RETENTION  
 TUMOR, BENIGN**

9. Mfr. report number  
**1999-02-0577**



**E. Initial reporter**

1. Name, address, and phone #  
 [REDACTED] R.P.H. [REDACTED]  
 [REDACTED] HOSPITAL  
 [REDACTED] AVENUE  
 UNITED STATES

2. Health Professional?  
 yes  no

3. Occupation  
**PHARMACIST**

4. Initial reporter also sent report to FDA  
 yes  no  unk



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



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

|                   |
|-------------------|
| Mfr. report #     |
| U/F Dist report # |
| FDA Use Only      |

**Patient information**

|  |  |  |                                 |
|--|--|--|---------------------------------|
| 1. Patient Identifier<br><br>in confidence | 2. Age at time of event:<br><br>Date of Birth: | 3. Sex<br><input type="checkbox"/> female<br><input type="checkbox"/> male | 4. Weight<br><br>lbs<br><br>kgs |
|--|--|--|---------------------------------|

**B. Adverse event or product problem**

Adverse event and/or  Product Problem (e.g. defects/malfunctions)

2. Outcome attributed to adverse event (check all that apply)

|   |   |
|---|---|
| <input type="checkbox"/> Death                                  | <input type="checkbox"/> Disability   |
| <input type="checkbox"/> Life-Threatening (mo/day/yr)           | <input type="checkbox"/> Congenital Anomaly   |
| <input type="checkbox"/> hospitalization - initial or prolonged | <input type="checkbox"/> required intervention to prevent permanent impairment/damage |
|   | <input type="checkbox"/> Other  |

3. Date of Event (mo/day/yr)      4. Date of this report (mo/day/yr)

5. Describe event or problem  
INDICATED THAT THE PATIENT "HAD NO PAST EXPOSURE TO HEPATITIS C". ON 4FEB, THE PATIENT TOOK 4 MG OF ATIVAM (LORAZEPAM) AT NIGHT INSTEAD OF THE 1 MG PRESCRIBED. THE FOLLOWING DAY (5FEB), THE PATIENT WAS TAKEN TO THE HOSPITAL BY HIS FAMILY FOR ACUTE MENTAL STATUS CHANGES. HE WAS STILL JAUNDICED AND WAS ADMITTED WITH A PRELIMINARY SUSPECTED DIAGNOSIS OF HEPATIC ENCEPHALOPATHY. ALL MEDICATIONS WERE DISCONTINUED. LACTULOSE 30 CC PO BID WAS ORDERED AND THE PATIENT WAS GIVEN ONE DOSE. APPROXIMATELY 12 HOURS AFTER ADMISSION HE WAS EVALUATED BY A GASTROENTEROLOGIST, WHO FOUND NO OTHER SYMPTOMS OF HEPATIC FAILURE, NO UPPER RIGHT QUADRANT TENDERNESS, NO GROSS SENSORY DEFICITS. THE PATIENT WAS ABLE TO CONVERSE LOGICALLY. AMMONIA LEVELS WERE WITHIN NORMAL LIMITS. HEPATIC ENCEPHALOPATHY WAS RULED OUT. NO LIVER BIOPSY WAS PERFORMED. THE PHYSICIAN REPORTEDLY RULED OUT OTHER RISK FACTORS FOR HEPATITIS (TRANSFUSIONS, ALCOHOL USE, TRAVEL, DRUG USE, NEEDLE EXPOSURE OR RECENT SHELLFISH INGESTION). THE GASTROENTEROLOGIST DIAGNOSED "SPONTANEOUSLY" RESOLVING HEPATITIS SECONDARY TO PLOMAX, BUT COULD NOT RULE OUT CLARITIN AS AN ALTERNATIVE AGENT. HE THOUGHT THE PATIENT'S ALTERED MENTAL STATUS WAS DUE TO AN INABILITY TO METABOLIZE ATIVAM AND PHENERGAN OR TO THE OVERDOSE OF ATIVAM IN COMBINATION WITH THE  
(CONTINUED)

6. Relevant tests/laboratory data, including dates

| PT         | 18.3 | 13.2  | 13.1  | --    |
|------------|------|-------|-------|-------|
| INR        | 1.43 | 1.23  | 1.21  | --    |
| NR3        | --   | 23    | --    | --    |
| TYLENOL    | --   | <10   | --    | --    |
| TEMP. (OF) | --   | 100.1 | 100.6 | 101.1 |

1FEB1999:  
HEPATITIS A SEROLOGIES: NEGATIVE  
HEPATITIS B SEROLOGIES: NEGATIVE  
(CONTINUED)

7. Other relevant history, including preexisting medical conditions, (e.g. allergies, race, neuromuscular, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
BLADDER PROBLEMS PRIOR TO OR DURING THE HOSPITALIZATION. PATIENT DID NOT USE ACETAMINOPHEN CHRONICALLY. THE PATIENT'S PHARMACIST INDICATED THE PATIENT'S PRIOR MEDICATION INCLUDED PAXIL (PAROXETINE; DISCONTINUED 3 MONTHS AGO [NOV1998]) AND LINORIL (SULINDAC; DISCONTINUED 3-4 WEEKS AGO [JAN1999]).

**C. Suspect medication(s)**

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

# 3 **TYLENOL EXTRA STRENGTH**

# 4 **CLARITIN (LORATADINE) TABLETS** (CONT)

2. Dose, frequency, route used

# 3 **8 TABLETS**

# 4 **10 MG ORAL**

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

# 3 **ONCE**

# 4 **01/24/1999-01/24/1999**

4. Diagnosis for Use (indication)

# 3 **UNKNOWN**

# 4 **HEADACHE**

5. Event abated after use stopped or dose reduced

# 3  yes  no  doesn't apply

# 4  yes  no  doesn't apply

6. Lot # (if known)

# 3

# 4

7. Exp. date (if known)

# 3

# 4

9. NDC # - for product problems only (if known)

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

**G. All manufacturers**

1. Contact office-name / address (mailing site for devices)

**SCHERING-PLOUGH CORPORATION**  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033

2. Phone Number  
**(973) 921-7435**

3. Report Source (check all that apply)

foreign  health professional

study  User facility

literature  Company representative

Consumer  distributor

Other:

4. Date received by manufacturer (mo/day/yr)

5. (A) NDA #

IND #

PLA #

pre-1938  yes

OTC product  yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day  15-day

10-day  periodic

Initial  follow-up#

8. Adverse Event Term(s)

9. Mfr. report number  
**1999-02-0577**

**E. Initial reporter**

1. Name of reporter

**RECEIVED**  
**JUN 10 1999**

2. Health Professional?

3. Occupation

4. Initial reporter also sent report to FDA  
 yes  no  unk





THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr. report #
U/F Dist report #
FDA Use Only

Patient information

1. Patient Identifier
2. Age at time of event
3. Sex
4. Weight

B. Adverse event or product problem

1. Adverse event and/or Product Problem
2. Outcome attributed to adverse event
3. Date of Event
4. Date of this report

5. Describe event or problem
HEPATITIS. ON 8FEB, THE PATIENT WAS DISCHARGED FROM HOSPITAL TO FOLLOW-UP WITH HIS PRIMARY CARE PHYSICIAN. AS OF 9FEB, THE PATIENT WAS RECOVERING FROM THE EVENT.

6. Relevant tests/laboratory data, including dates
UNSPECIFIED TEST FOR HEPATITIS C: "NO PRIOR EXPOSURE TO HEPATITIS C"
2FEB1999: CT SCAN-"INCIDENTAL" FINDING OF PARAPLEVIC CYST, OTHERWISE CT SCAN WAS UNREMARKABLE.

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

C. Suspect medication(s)

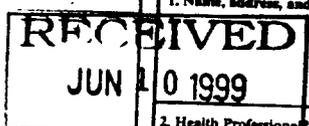
1. Name (give labeled strength, mfr/labeler, if known)
# 5 PHENERGAN
2. Dose, frequency, route used
# 5 12.5 MG PRN
3. Therapy dates (if unknown, give duration from/to (or best estimate)
# 5 01/26/1999-02/05/1999
4. Diagnosis for Use (indication)
# 5 NAUSEA AND VOMITING
5. Event abated after use stopped or dose reduced
# 5 [X] yes [ ] no [ ] doesn't apply
8. Event reappeared after reintroduction
# 5 [ ] yes [ ] no [X] doesn't apply

G. All manufacturers

1. Contact office-name / address (mfring site for devices)
SCHERING-PLOUGH CORPORATION
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033
2. Phone Number
(973) 921-7435
3. Report Source
[ ] foreign [ ] health professional
[ ] study [ ] User facility
[ ] literature [ ] Company representative
[ ] Consumer [ ] distributor
[ ] Other:
4. Date received by manufacturer (mo/day/yr)
5. (A) NDA #
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply)
[ ] 3-day [ ] 15-day
[ ] 10-day [ ] periodic
[ ] Initial [ ] follow-up#
8. Adverse Event Term(s)
9. Mfr. report number
1999-02-0577

E. Initial reporter

1. Name, address, and phone #
2. Health Professional
[ ] yes [ ] no
3. Occupation
4. Initial reporter also sent report to FDA
[ ] yes [ ] no [ ] unk



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