Individual Safety Report

3325137-X-00-01

Eli Lilly and Company

Approved by FDA on 3/22/94

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Mfr report # US_980706364

JF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: - - in confidence
2. Age at time of event: 68 yrs or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: NI lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [ ] death
   - [ ] life-threatening
   - [ ] hospitalization - initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other:
3. Date of event: ??/JUN/1998
4. Date of this report: 29/MAR/1999
5. Describe event or problem

THIS CASE, REPORTED BY A PHYSICIAN VIA A SALES REPRESENTATIVE, CONCERNS A 68 YEAR OLD CAUCASIAN FEMALE PATIENT. THE PATIENT RECEIVED RALOXIFENE (EVISTA) 60 MG DAILY FOR OSTEOPENIA FOR APPROXIMATELY FIVE MONTHS AND PROPOXYPHENE HYDROCHLORIDE (DARVOCET-N 100), ONE TO TWO TABLETS PER DAY, AS NEEDED, FOR A LUMBAR COMPRESSION FRACTURE, SINCE SEP 97.

APPROXIMATELY FOUR MONTHS AFTER BEGINNING RALOXIFENE THERAPY, THE PATIENT'S SGOT AND SGPT WERE ELEVATED (44 AND 151 RESPECTIVELY). THE PATIENT'S BASELINE LIVER ENZYME LEVELS WERE SGOT=20 AND SGPT=14 ON 29 AUG 97, APPROXIMATELY 10 MONTHS AGO. THE PHYSICIAN PLANNED A REPEAT OF THE BLOOD TESTS IN THREE MONTHS.
*

6. Relevant tests/laboratory data, including dates

Lab data:
Lab test or Procedure / Result Units / Date and Time / Reference to normal range

1) AST/SGOT, ASPARTATE AMINOTRANSFERASE /20 /29-AUG-1997/UNK *

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

Relevant history / Concurrent conditions:
BREAKTHROUGH BLEEDING (POSTMENOPAUSAL BLEEDING)
OSTEOPOROSIS (OSTEOPOROSIS)
BONE FRACTURE (LUMBAR COMPRESSION) (FX LUMBAR VERTEBRA, CLOSED) *

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 EVISTA(RALOXIFENE HYDROCHLORIDE)
   #2 DARVOCET-.(PROPOXYPHENE HYDROCHLORIDE)
2. Dose, frequency & route used
   #1 UNK
   #2 UNK
3. Therapy dates (if unknown, give duration)
   #1 10-FEB-98, continuing
   #2 ??-SEP-97 to NI
4. Diagnosis for use (indication)
   #1 OSTEOPENIA
   #2 LUMBAR COMPRESSION FRACTURE
5. Event abated after use stopped or dose reduced
   #1 [ ] yes [ ] no [X] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   #1 NI
   #2 NI
7. Exp. date (if known)
   #1 NI
   #2 NI
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)
   #1
   #2
10. Concomitant medical products and therapy dates (exclude treatment of event)

1) ADALAT(NIFEDIPINE)
Dose: 30 mg/DAY, Dates: ??-???-1995 Continuing,

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
   Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
2. Phone number: NI
3. Report source (check all that apply)
   - [ ] foreign
   - [ ] study
   - [ ] literature
   - [ ] consumer
   - [X] health professional
   - [ ] user facility
   - [X] company representative
   - [ ] distributor
   - [ ] other:
4. Date received by manufacturer: 29JUN98 (F/U:22DEC98)
5. (A)NDA # 20-815
   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 [X] periodic
   - [X] Initial [ ] follow-up #
8. Adverse event term(s)
   LIVER FUNCTION TESTS ABNORMAL
9. Mfr. report number: US_980706364

E. Initial reporter

1. Name, address & phone #
   Dr. [redacted]
   [redacted] AVENUE
   SUITE [redacted]
   [redacted] US
2. Health professional? [X] yes [ ] no
3. Occupation: MEDICAL DOCTOR
4. Initial reporter also sent report to FDA: [ ] yes [ ] no [ ] unk

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BY:

FDA

Domain Facsimile of FDA Form 3500A

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

Item completed on continuation pages.

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MEDWATCH	A.1. Patient identifier	G.9. Mfr. report number	
	- -	US_980706364	Page 2 of 2

B.5. Describe event or problem

[continuation:] UPON FOLLOW-UP IN SEP-1998 AND 22 DEC 1998, THE LIVER FUNCTION TESTS HAD RETURNED TO NORMAL. THE PATIENT HAS NOT HAD ANY MORE PROBLEMS. RALOXIFENE IS BEING CONTINUED.

PAST MEDICAL HISTORY: BREAKTHROUGH BLEEDING WHILE ON PREVIOUS USE OF HORMONE REPLACEMENT THERAPY IN DEC 97, DISCONTINUED JAN 98.

F/U 20 JUL 98: ADDED SUSPECT AND CONCOMITANT MEDICATION DOSAGES AND INDICATIONS AND PATIENT HISTORY. NO ADDITIONAL INFORMATION PROVIDED.
F/U 29-SEP-1998: ADDED OUTCOME OF EVENTS, RALOXIFENE CONTINUED.
F/U 22-DEC-1998: LIVER ENZYMES REMAIN NORMAL AND RALOXIFENE CONTINUED.
UPDATE 12-JAN-1999: CHANGED EVENT RELATEDNESS TO NO FOR RALOXIFENE AS EVENT ABATED WHILE CONTINUING DRUG.

B.6. Relevant tests/laboratory dataincluding dates

[continuation:] 2) AST/SGOT, ASPARTATE AMINOTRANSFERASE /44 /16-JUN-1998/UNK
3) ALT/SGPT, ALANINE AMINOTRANSFERASE/14 /29-AUG-1997/UNK
4) ALT/SGPT, ALANINE AMINOTRANSFERASE/151 /29-AUG-1997/UNK

B.7. Other relevant history, including preexisting medical conditidsg., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:]
OSTEOPENIA; LUMBAR COMPRESSION FRACTURE; BREAKTHROUGH BLEEDING WHILE ON PREVIOUS USE OF HORMONE REPLACEMENT THERAPY IN DEC 97, DISCONTINUED JAN 98.

Origin: CAUCASIAN

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BY: