## Chacon, Maureen

**From:** Pauline Wood [pwood@clinquest.com]
**Sent:** Friday, August 30, 2013 10:49 AM
**To:** LGMB
**Cc:** akrimax
**Subject:** Adverse Event Report for Levoxyl TIR-02146
**Attachments:** TIR-02146 Medwatch.pdf

**Categories:** Maureen

To Whom It May Concern:

Pursuant to the Guideline for Post-Marketing Reporting Adverse Drug Experiences, I am submitting a MedWatch with information received by Clinquest on behalf of Akrimax Pharmaceuticals regarding the above referenced products.

This report will be submitted to the FDA by Akrimax Pharmaceuticals for Tirosint (levothyroxine sodium).

We trust that you will protect the identity of the reporter, in accordance with applicable regulations.

If you have questions, please contact me at 1-888-373-1733.

Sincerely,

Pauline Wood
Pharmacovigilance and Medical Information Coordinator
Clinquest Inc.
One Cabot Road, Hudson, MA 01749
Fax: (978) 568-8206

US Department of Health and Human Services
Food and Drug Administration

# MEDWATCH

**Akrimax Pharmaceuticals, LLC**



Form Approved: OMB No. 0910-0291, Expires: 10/31/08
Clinquest Facsimile FDA Facsimile Approval: 10/26/07

Mfr. Report # TIR-02146

UF/Importer Report #

FDA Use Only

## A. PATIENT INFORMATION

| 1. Patient Identifier | 2. Age at Time of Event: | 3. Sex | 4. Weight |
|---|---|---|---|
| A-D | 80 years or Date of Birth: 04/24/1933 | ☒ Female ☐ Male | 119 lbs or kg |
| In confidence | | | |

## 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: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

| 3. Date of Event *(mm/dd/yyyy)* | 4. Date of This Report *(mm/dd/yyyy)* |
|---|---|
| | 06/25/2013 |

5. Describe Event or Problem

Thyroid levels low, Very soft bowel movement approximately 1 hour after taking Tirosint, Severe diarrhea at approximately 1 p.m.

Spontaneous report received on 03 June 2013 from an 80 year old female consumer (initials A-D, weight 119lbs, height 64in) who began treatment with Tirosint (levothyroxine sodium) 13mcg, 25mcg, 38mcg and 50mcg; taking one capsule daily and one strength at a time to gradually increase up to 50mcg, for hypothyroidism on unknown dates in 2012. The consumer's medical history is significant for experiencing diarrhea during prior treatment with Levoxyl (levothyroxine sodium) (date unknown) and diarrhea, hair loss and weight loss during prior treatment with Synthroid (levothyroxine sodium) (date unknown). Concomitant *[continued]*

6. Relevant Tests/Laboratory Data, Including Dates

Thyroid levels were low (date unknown)

*Laboratory results reported by consumer and not medically confirmed.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Experienced diarrhea during prior treatment with Levoxyl (levothyroxine sodium) (date unknown) and experienced diarrhea, hair loss and weight loss during prior treatment with Synthroid (levothyroxine sodium) (date unknown) Pregnant: No

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

**3500A Facsimile**

## C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 Tirosint (levothyroxine sodium) *[continued]*

#2 Tirosint (levothyroxine sodium) *[continued]*

| 2. Dose, Frequency & Route Used | 3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)* |
|---|---|
| #1 One *[continued]* | #1 UNK/UNK/2012 - |
| #2 One *[continued]* | #2 UNK/UNK/UNK - |

4. Diagnosis for Use *(Indication)*

#1 Hypothyroidism

#2 Hypothyroidism

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☒ Doesn't Apply

#2 ☒ Yes ☐ No ☐ Doesn't Apply

| 6. Lot # | 7. Exp. Date |
|---|---|
| #1 | #1 |
| #2 121002 | #2 |

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☒ Doesn't Apply

#2 ☒ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

Vitamin D: NI

## G. ALL MANUFACTURERS

1. Contact Office - Name/Address

Keith S. Rotenberg, Ph.D.
Chief Scientific Officer
Akrimax Pharmaceuticals, LLC
11 Commerce Drive
Cranford, NJ 07016

2. Phone Number: 908-372-1209

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 06/03/2013

5. (A)NDA # 21-924
IND # _____
STN # _____

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 7-day ☒ Periodic
☐ 15-day ☒ Initial
☐ Follow-up # _____

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

8. Adverse Event Term(s)

MedDRA PT(s): Thyroid function test abnormal, Diarrhoea, Diarrhoea

9. Manufacturer Report Number: TIR-02146

## E. INITIAL REPORTER

1. Name and Address

A-D
US

Phone #

| 2. Health Professional? | 3. Occupation | 4. Initial Reporter Also Sent Report to FDA |
|---|---|---|
| ☐ Yes ☒ No | NA | ☐ Yes ☐ No ☒ UNK |

B.5. Describe Event or Problem *[continued]*

medication included vitamin D.

A-D began taking Tirosint on an unknown date in 2012 for the treatment of hypothyroidism. A-D began taking Tirosint 13mcg and stated she did not have a problem. On unknown dates she was increased to 25mcg, 38mcg and then to 50mcg of Tirosint because her thyroid levels were low. A-D stated when she began taking Tirosint 50mcg she noticed that she would have a very soft bowel movement approximately one hour after taking the Tirosint. She would then have severe diarrhea at approximately 1 p.m. A-D stated the diarrhea continued while she was on Tirosint. A-D temporarily discontinued her Tirosint from 30 May 2013 through 02 June 2013 because she was traveling. A-D did not experience the soft bowel movement or diarrhea during the time she stopped Tirosint. A-D began taking Tirosint again on 03 June 2013. She stated that an hour after taking her Tirosint she experienced the soft bowel movement and then the diarrhea at 1 p.m. No further information was provided.

The reporter may be contacted again and their health care provider may be contacted as well.

C.1.#1. Name *[continued]*

Capsules, 13mcg, 25mcg, 38mcg; Akrimax

C.2.#1. Dose, Frequency & Route Used *[continued]*

capsule daily, oral

C.3.#1. Therapy Dates *[continued]*

UNK/UNK/UNK

C.1.#2 Name *[continued]*

Capsules, 50mcg; Akrimax

C.2.#2. Dose, Frequency & Route Used *[continued]*

capsule daily, oral

C.3.#2. Therapy Dates *[continued]*

Continuing