Christian, Nishi

From: Pauline Wood [pwood@clinquest.com]
Sent: Friday, August 30, 2013 1:04 PM
To: LGMB
Cc: akrimax
Subject: Adverse Event Report for Levoxyl (levothyroxine sodium) TIR-02420
Attachments: TIR-02420 Medwatch.pdf

Categories: Nishi

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.
1 Cabot Rd
Hudson MA, 01749
978-568-8880

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-02420
UF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
M-A In confidence	or Date of Birth:	☒ Female ☐ Male	lbs or kg

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)*
07/UNK/2013	08/06/2013

5. Describe Event or Problem

Bloated feeling

Spontaneous report received on 22 July 2013 from a female consumer (initials M-A, age not provided) who began treatment with Tirosint (levothyroxine sodium) 50mcg daily for hypothyroidism on 18 July 2013. The consumer's medical history is significant for burning in her chest in February 2013 while taking Levoxyl (levothyroxine sodium), which she took for 15 years; and prior treatment with Synthroid (levothyroxine sodium) with which she felt terrible. Concomitant medications were not provided.

M-A began taking Tirosint on 18 July 2013 for the treatment of hypothyroidism. She had been taking Levoxyl for 15 years. M-A reported that in February 2013 she began to experience a burning in her chest. M-A *[continued]*

6. Relevant Tests/Laboratory Data, Including Dates

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

Burning in chest in February 2013 while taking Levoxyl (levothyroxine sodium), which she took for 15 years
Prior treatment with Synthroid (levothyroxine sodium) with which she felt terrible
Pregnant: Unknown

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

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 One 50mcg *[continued]*	#1 07/18/2013 - Continuing
#2	#2

4. Diagnosis for Use *(Indication)*
#1 Hypothyroidism
#2

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	#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)*

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)*
07/22/2013

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): Abdominal distension

9. Manufacturer Report Number
TIR-02420

E. INITIAL REPORTER

1. Name and Address
M-A
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]*

mentioned the burning to her physician, and her physician did not think it was related to the Levoxyl. On an unknown date in May 2013, M-A accidentally missed a dose of her Levoxyl and she did not experience the burning in her chest. On an unknown date, M-A was discontinued from Levoxyl and switched to Synthroid 75mcg. M-A stated she took Synthroid and felt terrible while taking it and asked her physician to switch her to Tirosint. M-A began taking Tirosint 50mcg on 18 July 2013. She reported that shortly after taking Tirosint she began to have a bloated feeling. As of 22 July 2013, M-A was still feeling bloated. 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, 50mcg; Akrimax

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

capsule daily, oral