Christian, Nishi

From: Pauline Wood [pwood@clinquest.com]
Sent: Pauline Wood [pwood@clinquest.com]
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

Fulfilling the Promise of Medicine Together

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Akrimax Pharmaceuticals, LLC

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" .1		#2			1.4		
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7. Exp. D	ate		#2 🗆	Yes	□ No	□ Doesn'	t Apply
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MEDWATCH				Page	1 of 2		Mfr. Report #	TIR-0	2420
							UF/Importer R	eport#	
									FDA Use
A. PATIENT INFOR					C. SUSPECT PRODU				
	2. Age at Time	of Event:	3. Sex	4. Weight	1. Name (Give labeled s	trength & n	nfr/labeler)	,	
M-A	or-		⊠ Female	lbs	#1 Tirosint (le	vothyr	oxine soc	dium)	[continued]
	Date of Birth	1:	☐ Male	or kg	#2				
In confidence				^ ^{Ng}	2. Dose, Frequency & R	Route Use	d 3. The	rapy Da	tes (If unknown, give duration
B. ADVERSE EVEN					#1 One 50mcg [co	ontinu		•	<i>t estimate)</i> 2013 — Continuing
1. 🛮 Adverse Event		Product Proble		s/malfunctions)		JIICIIIU		/10/2	.013 - CONCINUIN
2. Outcomes Attribut					#2		#2		
☐ Death: ☐ Life-threatening	<u>/y/y)</u>	☐ Disability or P		-	4. Diagnosis for Use (In				nt Abated After Use ed or Dose Reduced?
_		Congenital Ar	-		#1 Hypothyroidis	sm		1	Yes 🛘 No 🗷 Doesn't Ap
☐ Hospitalization - initial or prolonge	ed l	☐ Other Serious	(Important M	edical Events)	#2			1	
3. Date of Event (mm/		4. Date of This	Report (mm/c	ld/yyyy)	6. Lot #	7. Exp. D	ate	#2 🗀	Yes D No Doesn't Ap
07/UNK/	2013	0	8/06/201	3	#1	#1			nt Reappeared After oduction?
5. Describe Event or I					#2	#2			Yes 🛘 No 🗷 Doesn't Ap
Bloated fee	ling				9. NDC# or Unique ID	-			
Spontaneous	renort ~	ecoimed a	n 22 T	1,,	ll ·				Yes 🛘 No 🗖 Doesn't Ap
2013 from a	female c	onsumer /	nı∠∠ ∪ü İnitial	s Ty	10. Concomitant Medica	al Product	s and Therapy	Dates (Exclude treatment of event)
M-A, age not	t provide	d) who be	egan						
treatment w:	ith Tiros	int (levo	thyroxi:						
sodium) 50m	cg daily	for hypot	hyroidi	sm on					
18 July 2013	3. The co	nsumer's	medical	,					
history is s chest in Feb	signilica orusry 20	nt for bu	rning i	n her					
Levoxyl (le	vothvroxi	ne sodium	Laking	h she					
took for 15	years; a	nd prior	treatme	nt					
with Synthro	oid (levo	thyroxine	sodium)	G. ALL MANUFACTU	IRERS			·
with which s				itant	1. Contact Office - Name				2. Phone Number
medications	were not	provided	١.		Keith S. Roten				908-372-1209
M-A began ta	akina Tir	osint or	18 .Ti11,	2013	Chief Scientif				
for the trea					Akrimax Pharma		als, LLC		3. Report Source (Check all that apply)
had been tal	king Levo	xyl for 1	5 years	. M-A	11 Commerce Dr:				☐ Foreign
reported that	at in Feb	ruary 201	3 she be	egan	Cranford, NJ 0	1016			Study
to experience	ce a burn	ing in he	r chest	. M-A					☐ Literature ☑ Consumer
fcontinuedl 6. Relevant Tests/Lab	oratory Data In	oludina Detec							☐ Health Professional
. Neievant resis/Lab	oratory Data, Inc	cidaing Dates			4. Date Received by		5.		☐ User Facility
					Manufacturer (mm/dd/yy	(YY)	(A)NDA # 21~	924	☐ Company Representati
					07/22/2013		IND#		☐ Distributor
				:	6. If IND, Give Protocol		CTN 4		☐ Other
							STN# Combination		
					7. Type of Report		Product	□Yes	
					(Check all that apply) 7-day Periodic		Pre-1938	□Yes	
					☐ 15-day 🛮 Initial	Ľ	OTC Product 8. Adverse Eve	☐Yes	(c)
					☐ Follow-up #	ľ			.
7. Other Relevant Hist	ory, Including P	reexisting Medic	cal Conditions	s (e.g.,	9. Manufacturer Report		MedDRA PI		Abdominal
allergies, race, pregnan	-	•	•		TIR-02420				
Burning in c									
taking Levox			sodium)	,	E. INITIAL REPORTE	R			
which she to Prior treatm			d		1. Name and Address		Phone #	#	
(levothyroxi				۷ ا	M-A		L		*****
felt terribl		,		-	US				
Pregnant: Un									
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Submission of a repor personnel, user facility	t does not cons	titute an admiss	ion that medi	cal	2. Health Professional?	3. Occup			Initial Reporter Also Sent
or contributed to the e	vent.	, manulat	rearer or prou	uor oaustu	☐ Yes 🏻 No		NA		☐ Yes ☐ No ☑ UNK
3500A Facsimile					I	I		1	

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. Report Number	Page 2 of 2
	M-A	TIR-02420	

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