URGENT VOLUNTARY RECALL: Pharmacy Level, November 07, 2024

Levothyroxine Sodium Tablets USP 75 mcg

Accord Healthcare, Inc. ("Accord Healthcare") is voluntarily recalling **one lot of Levothyroxine Sodium Tablets USP 75 mcg, at the Pharmacy Level.**

This recall is being initiated because out of specification result was observed during long term stability testing of Levothyroxine Sodium Tablets USP 75 mcg at 18 months. The out of specification result was observed on an assay conducted on lot D2300191 of Levothyroxine Sodium Tablets USP 75 mcg. The assay content of Levothyroxine Sodium Tablets for this lot was observed to be 94.6 %, which is outside of the specification range of 95.0% to 105.0 % set forth on the label. This means that the observed level of active ingredient in the product was below the approved specification when tested at 18 months, which may affect the efficacy of the medication. As patient safety is the highest priority, Accord Healthcare is taking immediate action to recall the affected product lot.

Please examine your inventory of Accord Healthcare's Levothyroxine Sodium Tablets USP 75 mcg for the below listed lot number carefully.

The product label for recalled product should have the following details, please refer to the enclosed product label included with this recall letter.

Levothyroxine Sodium Tablets USP				
Strength	**Bottle Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
75 MCG	1000 Tablets	16729-449-17	D2300191	12/2025

Pharmacy - Please perform the following activities:

- Examine your inventory immediately for the listed lot number of Levothyroxine Sodium Tablets USP 75 mcg.
- Immediately discontinue distribution of the recalled Lot number of Accord Healthcare's Levothyroxine Sodium Tablets USP 75 mcg, D2300191.
- Promptly complete the attached Product Recall Response Form and reply even if you have **NO** Product to return.
- If you do have product to return, complete the attached Product Recall Response Form, quarantine the stock and follow the instructions given on the recall response form.
- If you have further distributed this lot number to other retailers, please immediately contact your customers and advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached Product Recall Response Form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Please complete and return the enclosed "PRODUCT RECALL RESPONSE FORM" as soon as possible, but no later than five business days from receipt of this letter.

Completed Product Recall Response form should be emailed, or sent via FAX to INMAR,
Attn: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.
INMAR Email: rxrecalls@inmar.com. FAX: 1-817-868-5362.

If you have any questions about the logistics for returning affected lot or other issues, please call Recall Services at 1-844-964-3478, Monday – Friday (excluding holidays), 9am to 5 pm EST.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for the returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord Healthcare, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617
USA

Each tablet contains 75 mcg (0.075 mg) levothyroxine sodium USP.
See package insert for full prescribing information.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Protect from light and moisture.
Dispense in a tight, light-resistant container as described in USP.
Do not accept if seal over bottle opening is broken or missing.
Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.
Manufactured by:
Intas Pharmaceuticals Limited,
Camp Road, Selaqui,
Dehradun-248 197, INDIA.

NDC 16729-~~449~~-17

Levothyroxine Sodium Tablets, USP

75 mcg (0.075 mg)

Rx Only

1000 Tablets

accord

80 3556 1 8618340 INL095 Mfg. Lic. No.: 15/UA/SC/P-2006

Keep area blank &
varnish free for overcoding
Lot and EXP & Data matrix
50 X 30 mm

accord™

PRODUCT RECALL RESPONSE FORM

Product Recall Date: November 07, 2024 **Voluntary Recall: Pharmacy Level**

Levothyroxine Sodium Tablets USP				
Strength	**Bottle Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
75 MCG	1000 Tablets	16729-449-17	D2300191	12/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ **DEA #**_____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address_____

City_____ State_____

Zip_____

Contact Name (please print)_____ Telephone # _____

Contact Signature _____ **Date**_____

If you did not purchase the product directly from the Manufacturer, please complete the following section.

Purchased from: Name _____ DEA #_____

Address _____

City_____ State_____

Zip_____

Please check all appropriate boxes:

- ☐ I have read and understand the recall instructions provided in the letter.
- ☐ I have checked my stock and have quarantined inventory consisting of _____bottles/units.

Any adverse events associated with recalled product?

☐Yes ☐ NO If yes, please explain: _____

Please describe your business: _____

Accord Healthcare, Inc.
8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617, USA | www.accordhealthcare.us

I have checked my stock and:

_____Do not have any stock of recalled **items**.

OR

_____Have quarantined and listed in the box above the quantity of bottles/units of **Levothyroxine Sodium Tablets USP 75 mcg** and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed:_____

Please fax this form to 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 1-844-964-3478.