URGENT VOLUNTARY RECALL: Pharmacy Level, April 09, 2025

Levothyroxine Sodium Tablets USP 25 mcg, 50 mcg, 88 mcg and 112 mcg

Accord Healthcare, Inc. ("Accord Healthcare") is voluntarily recalling four lots of Levothyroxine Sodium Tablets USP 25 mcg, 50 mcg, 88 mcg and 112 mcg, at the Pharmacy Level.

This recall is being initiated because out of specification results were observed during long term stability testing of Levothyroxine Sodium Tablets USP for 25 mcg, 50 mcg, 88 mcg and 112 mcg. The out of specification results were observed on an assay conducted on four lots of Levothyroxine Sodium Tablets.

The assay content of Levothyroxine Sodium Tablets for lots D2300323 (25 mcg, 93.8% at 24 months), D2400547 (50 mcg, 94.7% at 9 months), D2300044 (88 mcg, 93.5% at 24 months), and D2400725 (112 mcg, 94.7% at 9 months) was observed below the approved specification range of 95.0%–105.0% set forth on the label. This means that the observed level of active ingredient in the product was below the approved specification.

These 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 lots.

Please examine your inventory of Accord Healthcare's Levothyroxine Sodium Tablets USP 25 mcg, 50 mcg, 88 mcg and 112 mcg for the below listed lot numbers carefully.

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

Levothyroxine Sodium Tablets USP				
Strength	**Bottle Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
25 mcg	1000 Tablets	16729-447-17	D2300323	01/2026
50 mcg	1000 Tablets	16729-448-17	D2400547	02/2026
88 mcg	1000 Tablets	16729-450-17	D2300044	12/2025
112 mcg	90 Tablets	16729-452-15	D2400725	03/2026

Pharmacy - Please perform the following activities:

- Examine your inventory immediately for the listed lot numbers of Levothyroxine Sodium Tablets USP 25 mcg, 50 mcg, 88 mcg and 112 mcg.
- Immediately discontinue distribution of the recalled Lot numbers of Accord Healthcare's Levothyroxine Sodium Tablets USP 25 mcg, 50 mcg, 88 mcg and 112 mcg.
- 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 them 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 1-877-645-8414, 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 25 mcg (0.025 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.,
Raleigh, NC 27617.
Manufactured by:
Intas Pharmaceuticals Limited,
Camp Road, Selaqui,
Dehradun-248 197, INDIA.

NDC 16729-**447**-17

Levothyroxine
Sodium Tablets, USP

25 mcg
(0.025 mg)

Rx Only

1000 Tablets

accord

80 3552 2 8618912 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

Each tablet contains 50 mcg (0.05 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.,
Raleigh, NC 27617.
Manufactured by:
Intas Pharmaceuticals Limited,
Camp Road, Selaqui,
Dehradun-248 197, INDIA.

NDC 16729-**448**-17

Levothyroxine
Sodium Tablets, USP

50 mcg
(0.05 mg)

Rx Only

1000 Tablets

accord

80 3554 2 8618937 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

Each tablet contains 88 mcg (0.088 mg) levothyroxine sodium USP.
See package insert for full prescribing information.
Contains FD&C Yellow No. 5 (tartrazine) as a color additive.
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.,
Raleigh, NC 27617.
Manufactured by:
Intas Pharmaceuticals Limited,
Camp Road, Selaqui,
Dehradun-248 197, INDIA.

NDC 16729-**450**-17

Levothyroxine
Sodium Tablets, USP

88 mcg
(0.088 mg)

Rx Only

1000 Tablets

accord

80 3565 2 8618923 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

Each tablet contains 112 mcg (0.112 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.,
Raleigh, NC 27617.
Manufactured by: Intas Pharmaceuticals Limited,
Camp Road, Selaqui, Dehradun-248 197, INDIA.

NDC 16729-**452**-15

Levothyroxine
Sodium Tablets, USP

112 mcg
(0.112 mg)

Rx Only

90 Tablets

accord

Mfg. Lic. No.: 15/UA/SC/P-2006
80 3565 2 8618922 INL087

Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
40 X 20 mm

PRODUCT RECALL RESPONSE FORM

Product Recall Date: April 09, 2025 **Voluntary Recall: Pharmacy Level**

Levothyroxine Sodium Tablets USP				
Strength	**Bottle Pack size**	**Product NDC**	**Lot No.**	**Expiry Date**
25 mcg	1000 Tablets	16729-447-17	D2300323	01/2026
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112 mcg	90 Tablets	16729-452-15	D2400725	03/2026

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: _____

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 25 mcg, 50 mcg, 88 mcg and 112 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:_____

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.

Even if you do not possess any inventory of the lot being recalled, we would appreciate it if you could still fill out and return the "PRODUCT RECALL RESPONSE FORM".

If you have any questions about the logistics for returning affected lot or other issues, please call Recall Services at 1-877-645-8414, Monday – Friday (excluding holidays), 9am to 5 pm EST.