



URGENT: DRUG MARKET WITHDRAWAL
[REVISED]

Liothyronine Sodium Tablets, USP 5 mcg and 25 mcg

December 5, 2023

Dear Customer,

This notice is to inform you of a product market withdrawal involving:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0044A	62756-589-88	12/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0045A	62756-589-88	12/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0139A	62756-589-88	01/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0140A	62756-589-88	02/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0141A	62756-589-88	02/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0687A	62756-589-88	05/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0688A	62756-589-88	05/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0689A	62756-589-88	05/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0690A	62756-589-88	05/2025



Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0043A	62756-589-88	12/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0138A	62756-589-88	01/2025
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DNE0686A	62756-589-88	05/2025
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND2171A	62756-590-88	11/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND2172A	62756-590-88	11/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DNC2205A	62756-590-88	11/2023
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0412A	62756-590-88	02/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0413A	62756-590-88	02/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0414A	62756-590-88	02/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0415A	62756-590-88	02/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0416A	62756-590-88	02/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0589A	62756-590-88	03/2024



Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0590A	62756-590-88	03/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0591A	62756-590-88	03/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0593A	62756-590-88	03/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND0594A	62756-590-88	03/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND1010A	62756-590-88	04/2024
Liothyronine Sodium Tablets, USP 25 mcg	100 tablets in 1 bottle	DND1011A	62756-590-88	04/2024

See enclosed product labeling.

This market withdrawal has been initiated in response to an Out of Trend (OOT) result reported for individual unknown impurity in Liothyronine Sodium Tablets, 25 mcg. A total of thirteen (13) batches of Liothyronine Sodium Tablets, USP 25 mcg were found to have Out of Trend (OOT) results but still within specification limit of NMT 1.0%. An additional fourteen (14) batches of Liothyronine Sodium Tablets, USP 5 mcg (12 batches) and 25 mcg (2 batches) used a different lot of labels but from the same label vendor. Therefore, as an out of abundance of caution, a market withdrawal is being recommended for all twenty-seven (27) batches in scope.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on March 2, 2022.

Immediately examine your inventory and quarantine product subject to market withdrawal. In addition, if you have further distributed this product, please identify your wholesale customers and notify them at once of this product market withdrawal. Your notification to your wholesale customers may be enhanced by including a copy of this market withdrawal notification letter.

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-780-4395 Monday to Friday from 8:30 am to 5:00 pm (EST).



Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

This market withdrawal should be carried out to the wholesale level.

Your assistance is appreciated and necessary to prevent patient harm.

This market withdrawal is being made with the knowledge of the Food and Drug Administration.

A handwritten signature in cursive script that reads "Christopher Leonor".

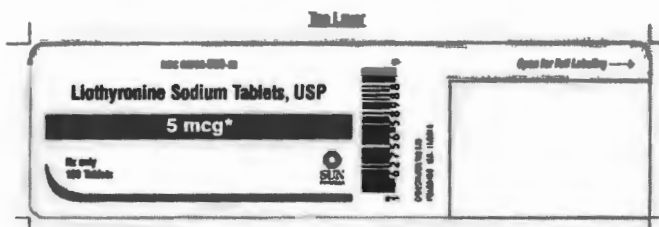
12/05/2023

Christopher Leonor
Sun Pharmaceutical Industries, Inc.
Associate Director, North America Supply Chain Quality & FDA Liaison

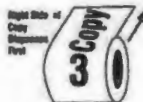
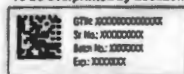
If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-780-4395.

Enclosures:

Liothyronine Sodium Tablets, USP 5 mcg: Label



To be overprinted by Location

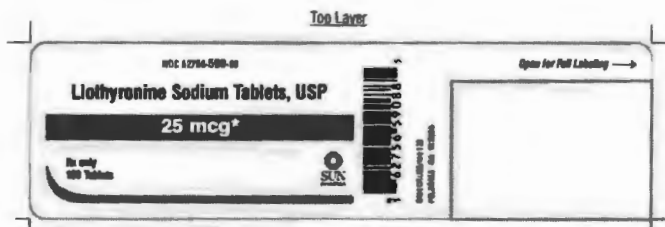


Size: 115x32 mm
[CRC]

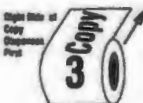
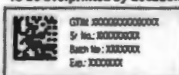
[Multi-Layer]

Unvarnish area: 37x25 mm

Liothyronine Sodium Tablets, USP 25 mcg: Label



To be overprinted by Location



Size: 115x32 mm
[CRC]

[Multi-Layer]

Unvarnish area: 37x25 mm

For return of affected product, please email rxrecalls@inmar.com or call 1-877-780-4395.



URGENT: DRUG MARKET WITHDRAWAL - RESPONSE FORM [REVISED]

**Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com**

Please check ALL appropriate boxes.

- I have read and understand the market withdrawal instructions provided in the December 5, 2023 letter.
- I have checked our stock and have quarantined inventory consisting of _____ units (number of full cartons) or _____ prescription packs (partial cartons).
- Indicate disposition of market withdrawal product:
 - returned (**specify quantity, date and method**)/held for return;
Number of Labels Required for Return to Inmar: _____
 - previously destroyed (**specify quantity, date and method**);
- I have identified and notified my wholesale customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or
 - Attached is a list of wholesale customers who received/may have received this product. Please notify my customers.

Any adverse events associated with market withdrawal product? Yes No
If yes, please explain: _____

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RESPONSE FORM [REVISED]

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Please check the appropriate box(es) to describe your business

- | | |
|---|--|
| <input type="checkbox"/> wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> grocery corporate headquarters | <input type="checkbox"/> hospital pharmacies |
| <input type="checkbox"/> repacker | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> pharmacy | <input type="checkbox"/> Other: |

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Email Address: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

Event ID RCL249-23 / N131006

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