GRANULES
PHARMACEUTICALS INC

3701 & 3725 Concorde Parkway
Chantilly, VA 20151
Phone No. 571-325-5950
Fax No.703-378-1578

# URGENT DRUG PRODUCT RECALL

June 24, 2025

Dear Customer,

This is to inform you that Granules Pharmaceuticals Inc. is voluntarily recalling below product:

| | |
|---|---|
| Drug Product Name | Metoprolol Succinate Extended-Release Tablets USP, 25 mg |
| ANDA / NDA Number | 216916 |
| Firm Drug Product Code | 140 |
| Dosage Form | Tablets |
| Lot Numbers | 1400008A and 1400008B |
| Intended Use/ Indications | Metoprolol Succinate Extended-Release Tablets USP, 25 mg is a beta-blocker used to treat chest pain (angina), heart failure, and high blood pressure. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. |
| Description of Product | White to off white, oval shaped, film coated scored tablets, debossed with "I" and "25" on either side of score line on one side and score line on other side. Free from physical defects |
| Package Type and Sizes/Number of Doses | 100 and 500 counts in HDPE bottle |
| NDC Number | 70010-780-01 and 70010-780-05 |

The recall is initiated due to Metoprolol Succinate ER Tablets 25mg, batch number #1400008A (100-count), failed to meet dissolution acceptance criteria in the stability studies at the 6th month (25°C/60% RH) long-term. Consequently, batch number #1400008B (500-count), also manufactured from the same bulk batch #1400008. No adverse events have been received to-date for the above-mentioned product lot.

Shipping date, Quantity, Manufacturing date and Expiry date of the impacted product lot are as follows:

| Batch Number | First Ship Date | Last Ship Date | Shipped Quantity | Mfg. Date | Exp. Date |
|---|---|---|---|---|---|
| 1400008A | 07/18/2024 | 11/18/2024 | 27648 Bottles | 01/2024 | 2025/12 |
| 1400008B | 07/26/2024 | 08/05/2024 | 5376 Bottles | 01/2024 | 2025/12 |

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

We request you to collect the entire recalled product and provide reconciliation of the product received. Kindly request a Qualanex (Inmar) LLC, Return Authorization by emailing Qualanex@recall.com. The returned recall product should be returned to Qualanex (Inmar) LLC, 1410, Harris Rd, Libertyville, IL – 60048 by using the

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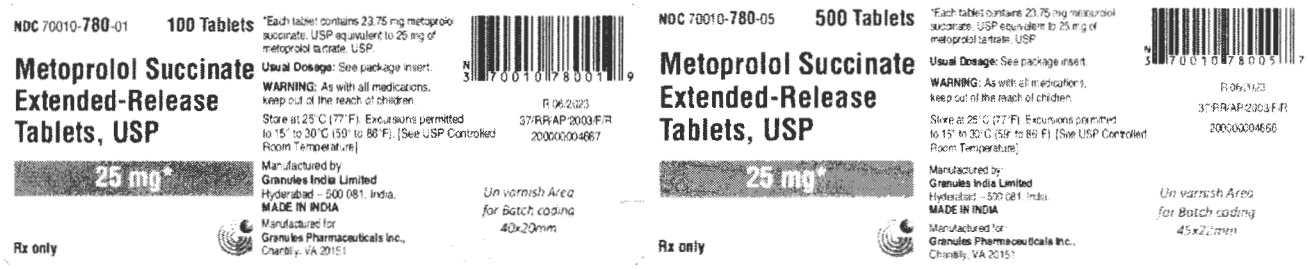
Return Authorization Notification Form. Provide the recalled product details by completing the enclosed recall response form.

This recall should be carried out to the retail level.

Included below are the labels associated with the recalled product.




Your assistance is appreciated and necessary to prevent consumer illness or patient harm.

Please complete and return the enclosed response form and email it to sandeep.uppaluri@granulesindia.com or fax at 703-378-1578. If you have any questions, please contact with the below mentioned communication details,

Sandeep Uppaluri
Tel: 571-752-6816, Email: Sandeep.uppaluri@granulesindia.com

For Adverse Event (ADE) Reporting, please contact 877-770-3183

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

Rajesh Kapoor Digitally signed by Rajesh Kapoor
Date: 2025.06.24 08.19.23 -04'00'

Rajesh Kapoor
Global Quality Head, Granules

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**Recall Return Response Form**

June 24, 2025

| | |
|---|---|
| Drug Product Name | Metoprolol Succinate Extended-Release Tablets USP, 25 mg |
| Lot Numbers | 1400008A and 1400008B |
| Expiry Date | December, 2025 |
| Description of Product | White to off white, oval shaped, film coated scored tablets, debossed with "I" and "25" on either side of score line on one side and score line on other side. Free from physical defects |
| Package Type and Sizes/Number of Doses | 100 and 500 counts in HDPE bottle |
| NDC Number | 70010-780-01 and 70010-780-05 |

**Please check ALL appropriate boxes.**
**Please complete this form and fax it back to 1-703-378-1578 or email to Sandeep.uppaluri@granulesindia.com**

□ I have read and understand the recall instructions provided in the June 24, 2025 letter.

□ I have checked my stock and have quarantined inventory consisting of above lot numbers.

□ Quantity Held for return (**specify quantity in the below table)**

| Lot Number | Quantity on Hand |
|---|---|
| 1400008A | |
| 1400008B | |

□ I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**): _____

Facility/Distribution Center Name: _____

Address: _____

Personnel Name: _____

Title: _____

Email ID: _____

Tel. number: _____

Signature: _____ Date: _____