



URGENT: DRUG RECALL

Lurasidone Hydrochloride Tablets 60 mg and 120 mg

January 16, 2024

Dear Customer,

This notice is to inform you of a product recall involving:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Lurasidone Hydrochloride Tablets 60 mg	30 count	DNE0620A	47335-639-83	05/2025
Lurasidone Hydrochloride Tablets 120 mg	30 count	DNE0621A	47335-579-83	11/2024
Lurasidone Hydrochloride Tablets 120 mg	30 count	DNE0815A	47335-579-83	12/2024

See enclosed product labeling.

This recall has been initiated in response to microbial contamination in stagnant water found in the duct of the manufacturing equipment.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on September 8, 2023.

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

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

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-811-1320 Monday to Friday from 8:30 am to 5:00 pm (EST).



This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

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

Christopher Leonor

01/16/2024

Christopher Leonor

Sun Pharmaceutical Industries, Inc.

Associate Director, North America Supply Chain Quality & FDA Liaison



Enclosure:

Lurasidone Hydrochloride Tablets 60 mg: Bottle Labeling

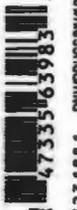
NDC 4735-639-83

Lurasidone Hydrochloride Tablets

60 mg

PHARMACIST: Dispense with Medication Guide to each patient.

Rx only
30 Tablets



4735639834
5231881 DMVDRUGS/MV138

Open for Full Labeling →



GTIN XXXXXXXXXX
SN XXXXXXXX
LOT AAAPBA
EXP MM/YYYY

Expiry to be overprinted
in MM/YYYY format

PEEL HERE

10MM GLUE AREA

10MM GLUE AREA

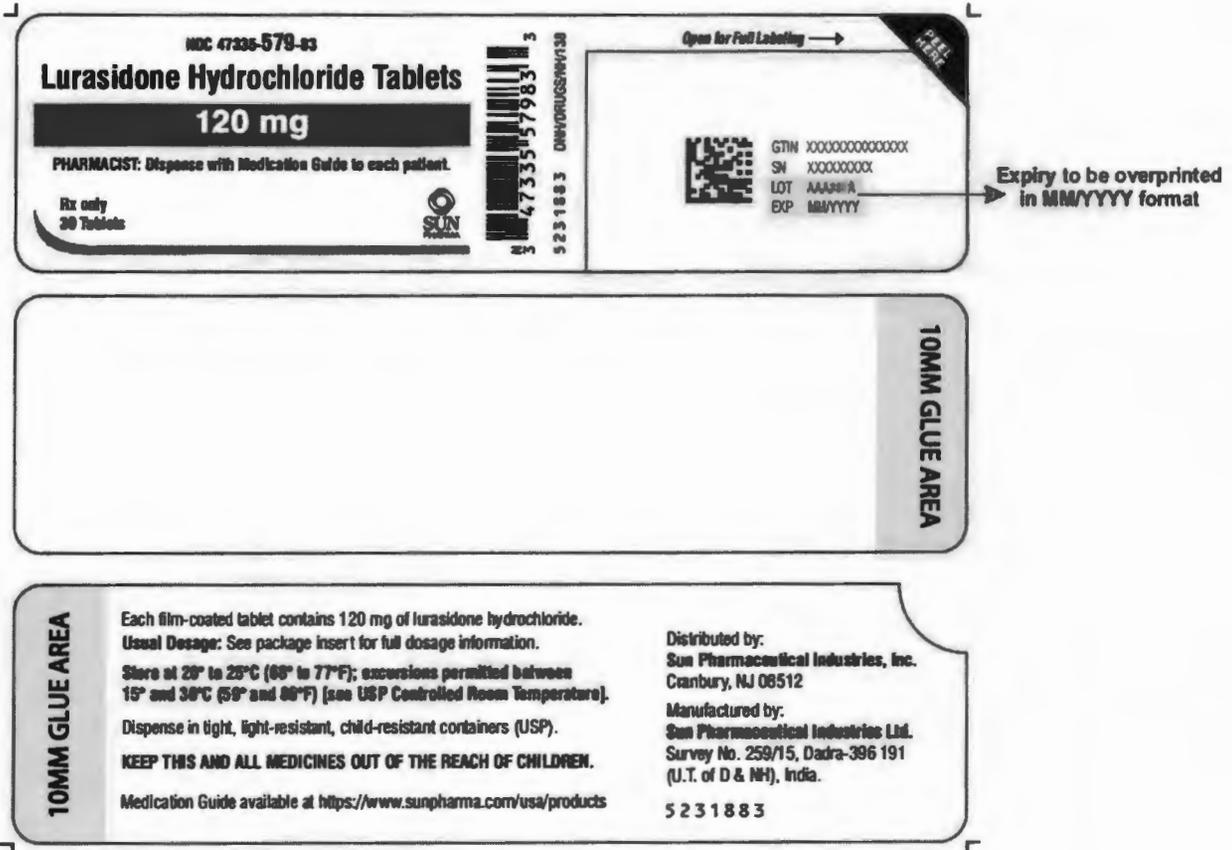
Each film-coated tablet contains 60 mg of lurasidone hydrochloride.
Usual Dosage: See package insert for full dosage information.
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].
Dispense in tight, light-resistant, child-resistant containers (USP).
KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Medication Guide available at <https://www.sunpharma.com/usa/products>

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Manufactured by:
Sun Pharmaceutical Industries Ltd.
Survey No. 259/15, Dadra-396 191
(U.T. of D & NH), India.

5 2 3 1 8 8 1

Lurasidone Hydrochloride Tablets 120 mg: Bottle Labeling



NDC 47335-579-83

Lurasidone Hydrochloride Tablets

120 mg

PHARMACIST: Dispense with Medication Guide to each patient.

Rx only
30 Tablets

5231883

Open for Full Labeling →

PEEL HERE

GTIN XXXXXXXXXX
SN XXXXXXXX
LOT AAAAAA
EXP MM/YYYY

Expiry to be overprinted in MM/YYYY format

10MM GLUE AREA

10MM GLUE AREA

Each film-coated tablet contains 120 mg of lurasidone hydrochloride.
Usual Dosage: See package insert for full dosage information.
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) (see USP Controlled Room Temperature).
Dispense in tight, light-resistant, child-resistant containers (USP).
KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Medication Guide available at <https://www.sunpharma.com/usa/products>

Distributed by:
Sun Pharmaceutical Industries, Inc.
Canbury, NJ 08512

Manufactured by:
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Survey No. 259/15, Dadra-396 191
(U.T. of D & NH), India.

5231883

For return of affected product, please email rxrecalls@inmar.com or call 1-877-811-1320.



URGENT: DRUG RECALL – RESPONSE FORM

**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 recall instructions provided in the January 16, 2024 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 recalled 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 retail customers that were shipped or may have been shipped this product by (specify date and method of notification); or

Attached is a list of retail customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? Yes No

If yes, please explain: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-877-811-1320.



URGENT: DRUG RECALL - RESPONSE FORM

Product Name	Package Description	Lot Number	NDC Number	Expiration Date	Total Number of Units (number of full cartons) or prescription packs (partial cartons)
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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: RCL007-2024 / N131125