SUN PHARMA

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.

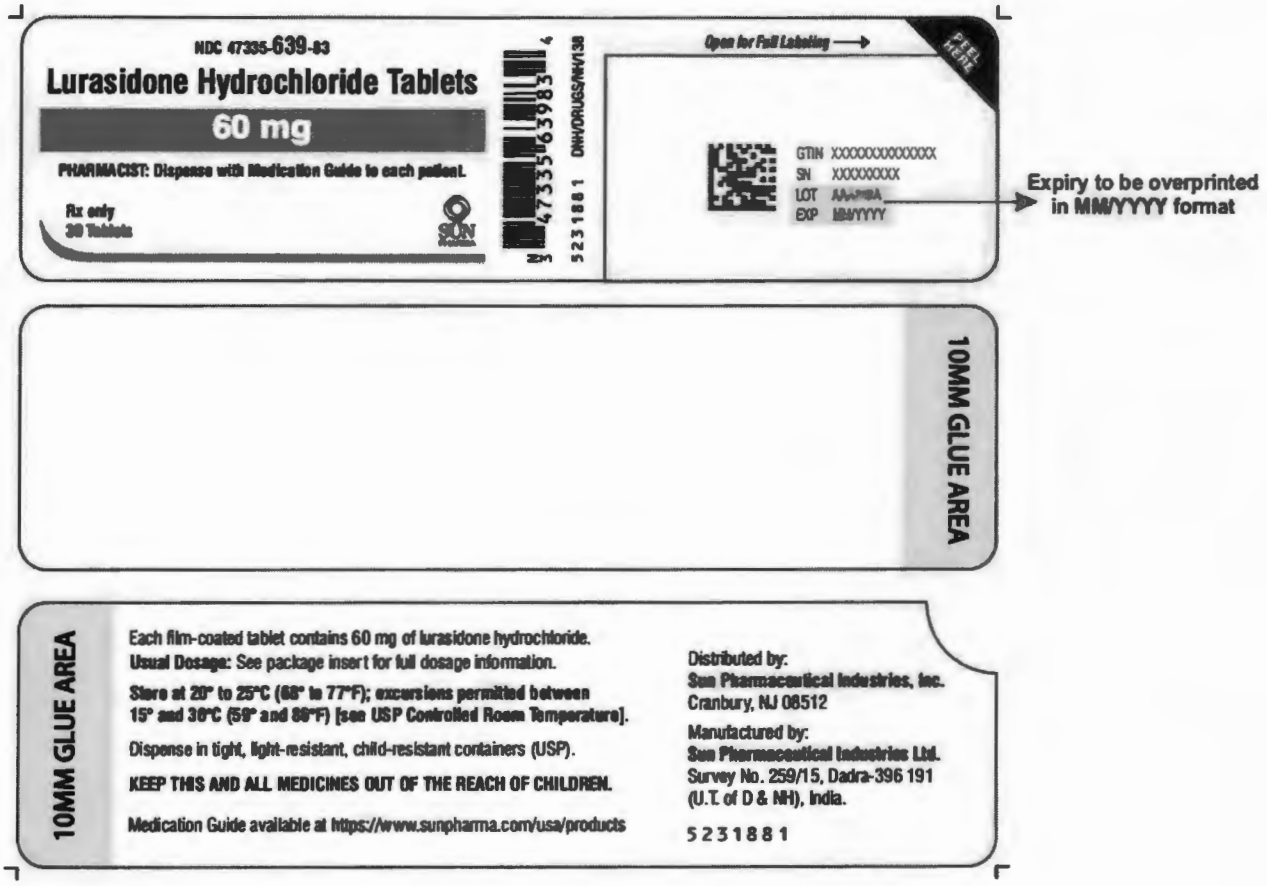
This recall is being made with the knowledge of the Food and Drug Administration.

Christopher Leonor 01/16/2024

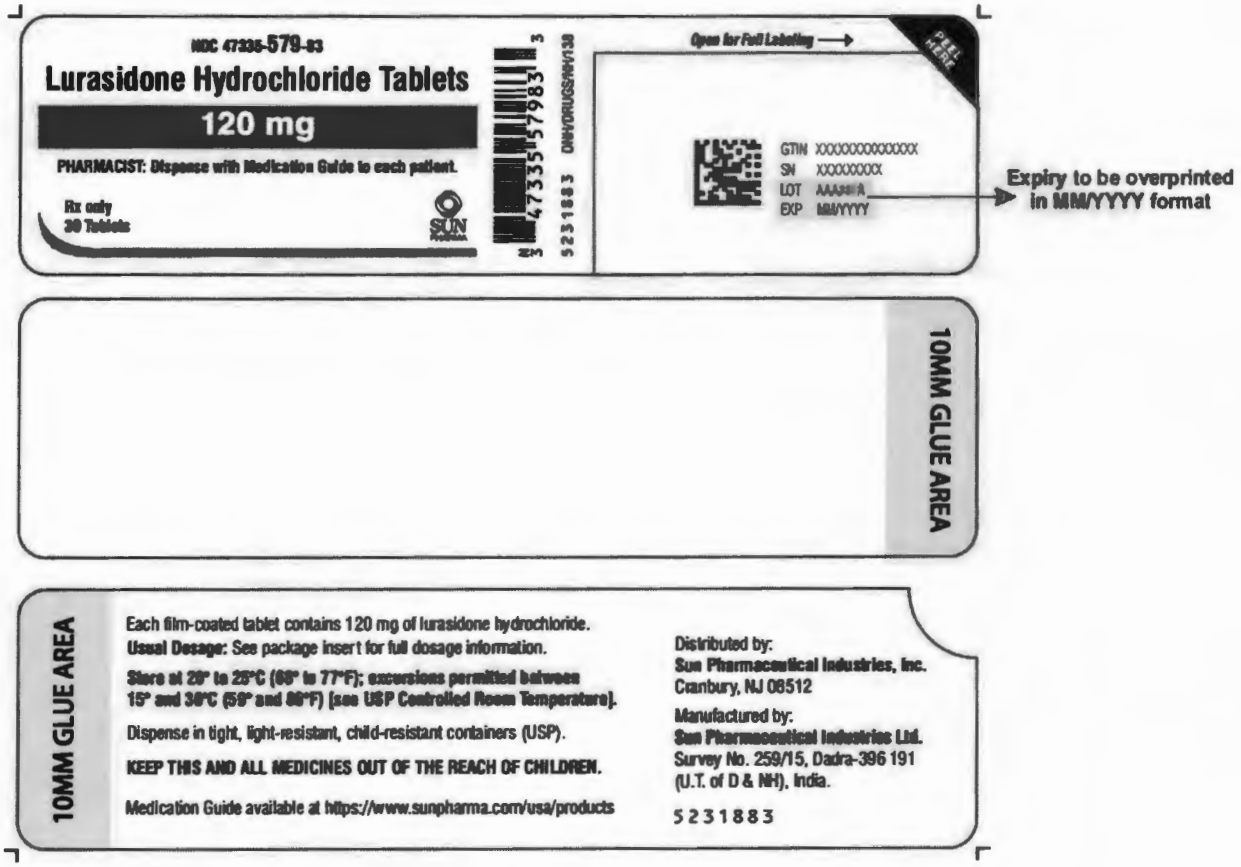
Christopher Leonor
Sun Pharmaceutical Industries, Inc.
Associate Director, North America Supply Chain Quality & FDA Liaison

Enclosure:

Lurasidone Hydrochloride Tablets 60 mg: Bottle Labeling



Lurasidone Hydrochloride Tablets 120 mg: Bottle Labeling



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

SUN PHARMA

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.

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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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Lurasidone Hydrochloride Tablets 120 mg	30 count	DNE0815A	47335-579-83	12/2024	

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

- □ wholesaler/distributor
- □ grocery corporate headquarters
- □ repacker
- □ pharmacy
- □ retailer
- □ hospital pharmacies
- □ hospital/medical facility
- □ 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