SUN PHARMA

URGENT: DRUG RECALL

Tiagabine Hydrochloride Tablets 2 mg

July 10, 2023

Dear Customer,

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

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Tiagabine Hydrochloride Tablets 2 mg	30 count bottle	HAC3339A	62756-200-83	07/2023

See enclosed product labeling.

This recall has been initiated in response to an Out of Specification (OOS) result observed during Related Substances testing of Tiagabine Hydrochloride Tablets, 2 mg, Batch HAC3339A, 18M 25°C/60%RH.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on October 25, 2021.

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 1-855-274-1944 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.

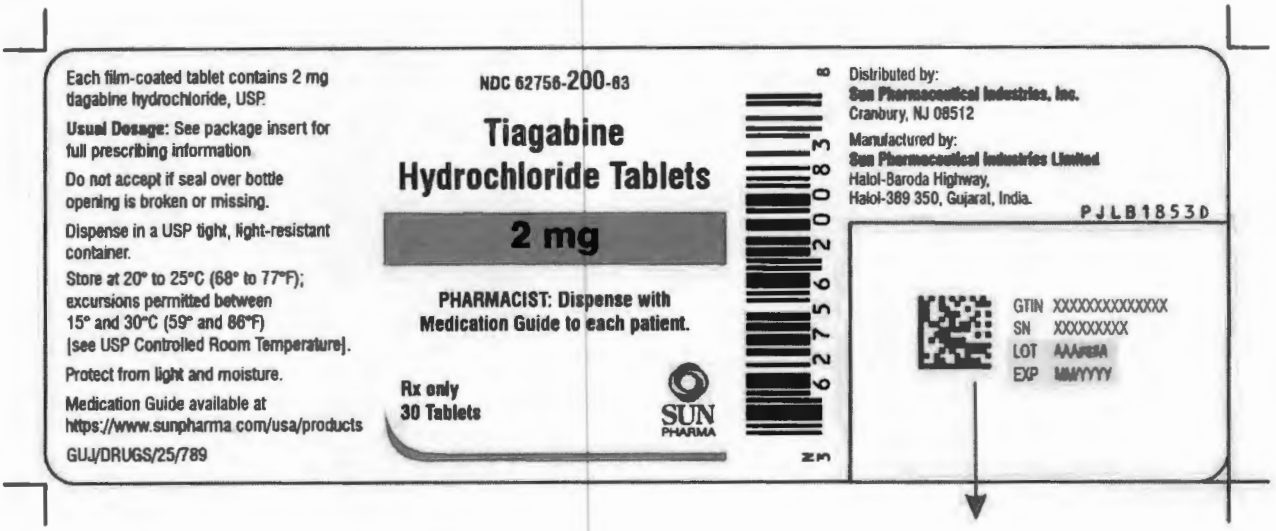
This recall is being made with the knowledge of the Food and Drug Administration.

Christopher Leonor 07/10/2023

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

For return of affected product, please email rxrecalls@inmar.com or call 1-855-274-1944.

Enclosure:
Tiagabine Hydrochloride Tablets 2 mg: Label



For return of affected product, please email rxrecalls@inmar.com or call 1-855-274-1944.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM

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

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Tiagabine Hydrochloride Tablets 2 mg	30 count bottle	HAC3339A	62756-200-83	07/2023

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the July 10, 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 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: _____

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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 Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

Recall Event ID RCL140-23 / N130951

For return of affected product, please email rxrecalls@inmar.com or call 1-855-274-1944.