URGENT: DRUG RECALL

Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)

Vecuronium Bromide for Injection, 20 mg (10 x 20 mg vials, lyophilized powder)

January 2, 2019

Dear Customer,

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

Product Name	Brand Name	Lot Number	NDC Number	Expiration Date
Vecuronium Bromide for Injection, 20 mg (10 x 20 mg vials, lyophilized powder)	N/A	JKS0400A	47335-932-44 [carton] 47335-932-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	N/A	JKS0443A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	N/A	JKS0444A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	N/A	JKS0477A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019

See enclosed product labeling.

This recall has been initiated due to foreign matter identified as glass detected in one (1) vial to date. Use of this product can possibly pose a risk to patient safety.

Sun Pharma initiated shipment of this product on December 19, 2017.

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, Inc.
4332 Empire Road
South Dock
Fort Worth, TX 76155

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-800-967-5952, 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.

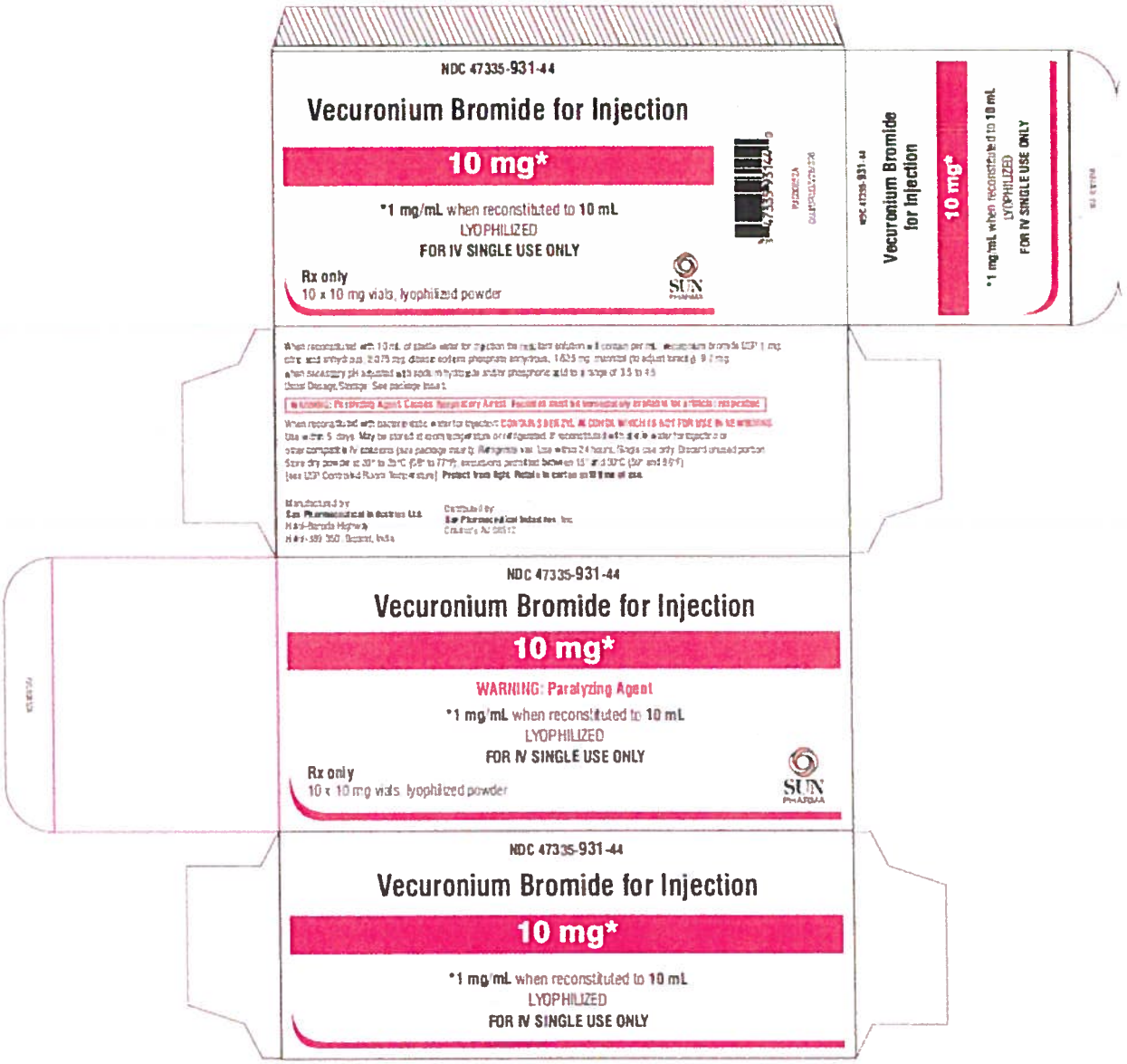
This recall is being made with the knowledge of the Food and Drug Administration.

Kristy Zielny
Sun Pharmaceutical Industries, Inc.
Director, Site Head of Quality, Cranbury
Enclosure

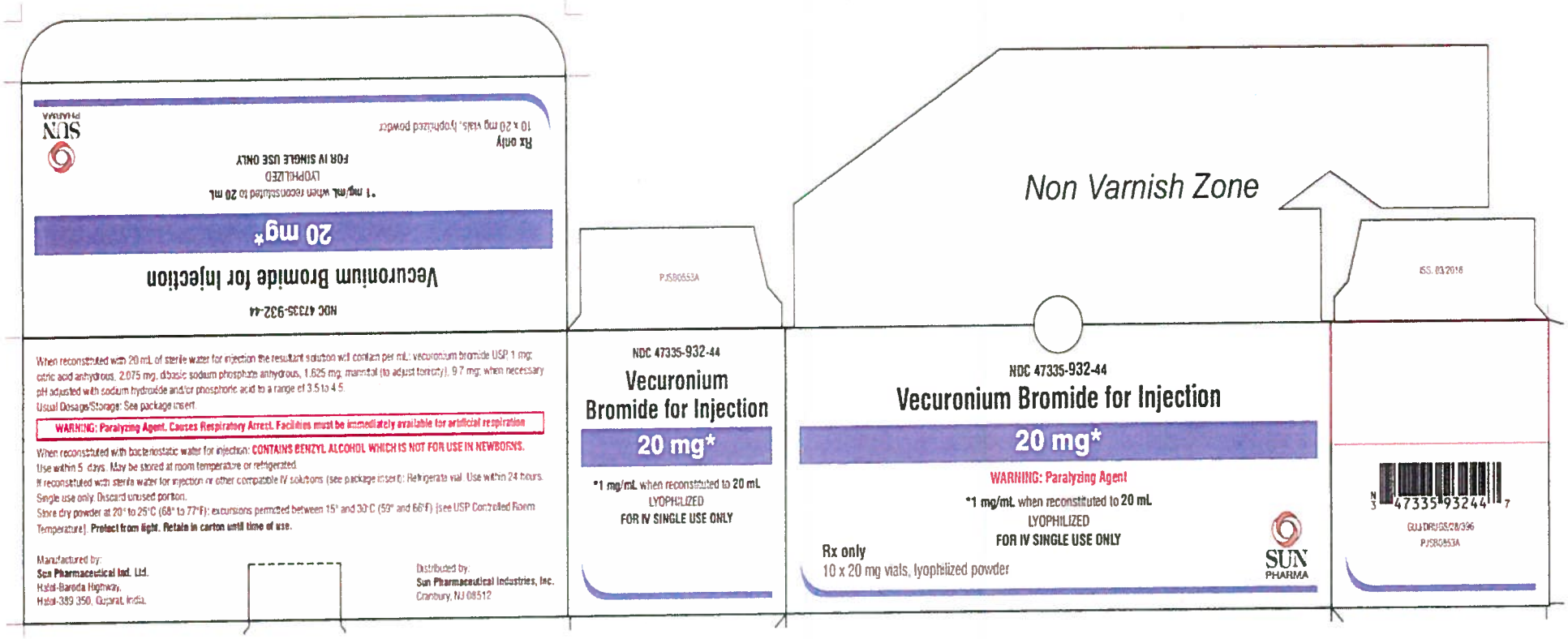
For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Enclosure:

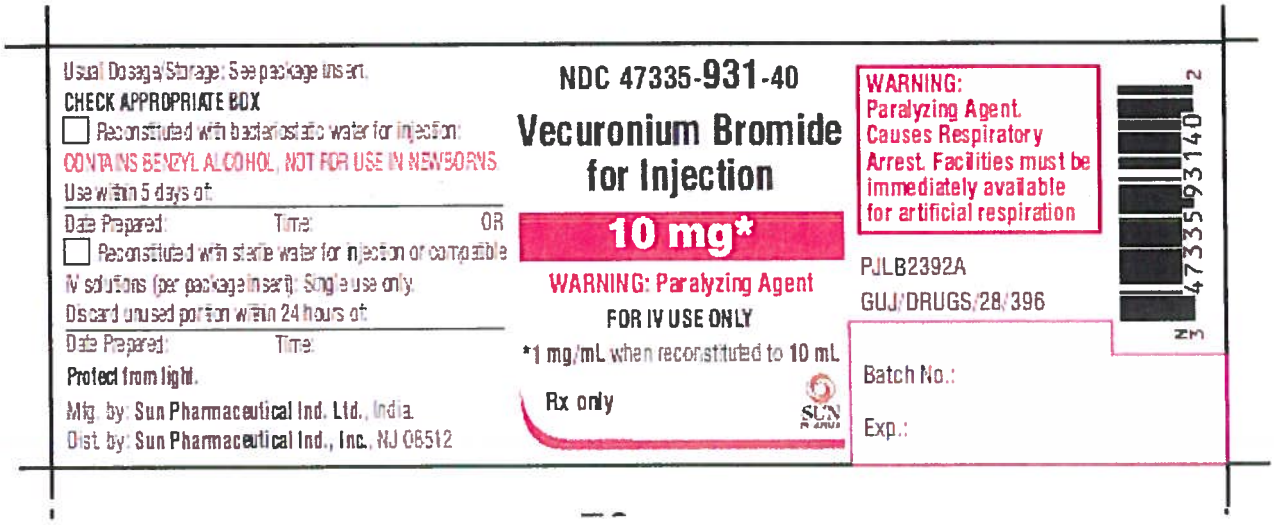
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder) Carton Labeling



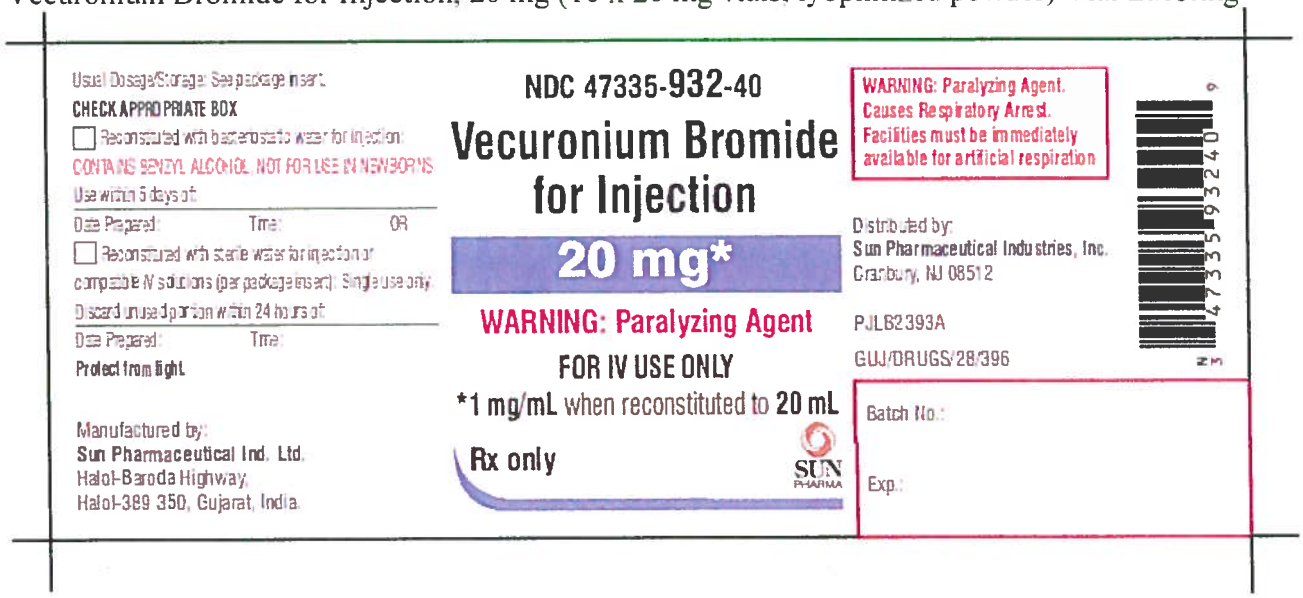
Vecuronium Bromide for Injection, 20 mg (10 x 20 mg vials, lyophilized powder) Carton Labeling



Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder) Vial Labeling



Vecuronium Bromide for Injection, 20 mg (10 x 20 mg vials, lyophilized powder) Vial Labeling



URGENT: DRUG RECALL – RESPONSE FORM

SUN PHARMA

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

Product Name	Lot Number	NDC Number	Expiration Date
Vecuronium Bromide for Injection, 20 mg (10 x 20 mg vials, lyophilized powder)	JKS0400A	47335-932-44 [carton] 47335-932-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	JKS0443A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	JKS0444A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019
Vecuronium Bromide for Injection, 10 mg (10 x 10 mg vials, lyophilized powder)	JKS0477A	47335-931-44 [carton] 47335-931-40 [vial]	03/2019

Please check ALL appropriate boxes

□ I have read and understand the recall instructions provided in the January 2, 2019 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**);

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

URGENT: DRUG RECALL – RESPONSE FORM

SUN PHARMA

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

□ 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: _____

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: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Recall/Withdrawal Initiation Form

Manufacturer Contact: Richard Lewellyn (Sales); Aimee Albanese (Quality) _____

Company Name: Sun Pharmaceutical Industries, Inc. _____

Address: 3 Skyline Drive _____

City: Hawthorne _____ State: NY_____ Zip:10532_____

E-Mail Address: Richard.lewellyn@taro.com; aimee.albanese@sunpharma.com_____

PO Number: _____

Product recalled or withdrawn: Vecuronium Bromide for Injection, 20 mg and 10 mg

UPC/NDC Codes(s): **Lot Code(s):** **Expiration Date**

47335-932-44 (Carton) and 47335-932-40 (vial), Lot JKS0400A, Expires 03/2019
47335-931-44 (Carton) and 47335-931-40 (vial), Lot JKS0443A, Expires 03/2019
47335-931-44 (Carton) and 47335-931-40 (vial), Lot JKS0444A, Expires 03/2019
47335-931-44 (Carton) and 47335-931-40 (vial), Lot JKS0477A, Expires 03/2019

Notification Level of Recall

☐ 1 Consumer ☒ 2 Retailer ☐ 3 Wholesaler

Projected Number of Consignees:

☒ US 66 Direct Consignees ☐ Canada _____ ☐ Other _____

Projected Quantity of Items to be returned: Maximum 13906 cartons; Estimated > 10% returned since this product is already considered short-dated.

Reason for Recall/Withdrawal:

This recall has been initiated due to foreign matter identified as glass detected in one (1) vial to date. Use of this product can possibly pose a risk to patient safety.

Party Issuing notification:

☐ Manufacturer to Notify

☒ Inmar Services to Notify

Notification Method:

☒ Overnight Delivery	☐ Fed Ex	Account #_____
☐ 2nd Day Delivery	☐ Fed Ex	Account#_____
☐ Express Saver 3 Day Delivery	☐ Fed Ex	Account#_____

☐ Other_____

Return Receipt Tracking?

☒ Yes ☐ No

Business Reply Forms included in mailing?

☒ YES ☐ NO

Product Retrieval Method

☐ Store Pickups ☒ Return Kits ☐ Not Applicable

Kit Instructions

Contents: Processing Label, Prepaid Shipping Label, and Instruction Letter

Return Shipping Included: _____

Return Method: Fed EX Ground

Manufacturer fed-ex account number for return shipping label: _____

Product Disposition Instructions (Complete all that apply):

☒ Quarantine to destroy with FDA approval.

☐ Return to Manufacturer:

Contact Name _____

Address _____

Phone Number _____

Disposal

☐ Destroy after _____ days ☐ Destroy upon receipt

☐ Hazardous Incineration ☐ Proof of Destruction Required ☐ Witnessed

☐ Non-Hazardous Incineration ☒ Proof of Destruction Required ☐ Witnessed

☐ Compacting Dumpster

Reports Frequency: Daily Format: Web

1) Return Authorizations (RA) Issued
2) Product Inventory (Claimed and Processed)
3) Payment/Credit Summary (if applicable)
4) Consignee Notification Summary/Business Reply Card Responses
5) Efficacy Checks (Call Notes and Comments)

Effectiveness Checks

☒ Yes ☐ NO 2nd mailing required? If yes, When? No second mailing required.

☐ Manufacturer to conduct calls ☒ Inmar to conduct calls

When to start calls? 45 days after initiation

MANUFACTURER Contact: _____ Date: 01-02-19

Form Received by: _____ Date: _____

Procedures Implemented by: _____ Date: _____

Recall Closed by: _____ Date: _____