



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.

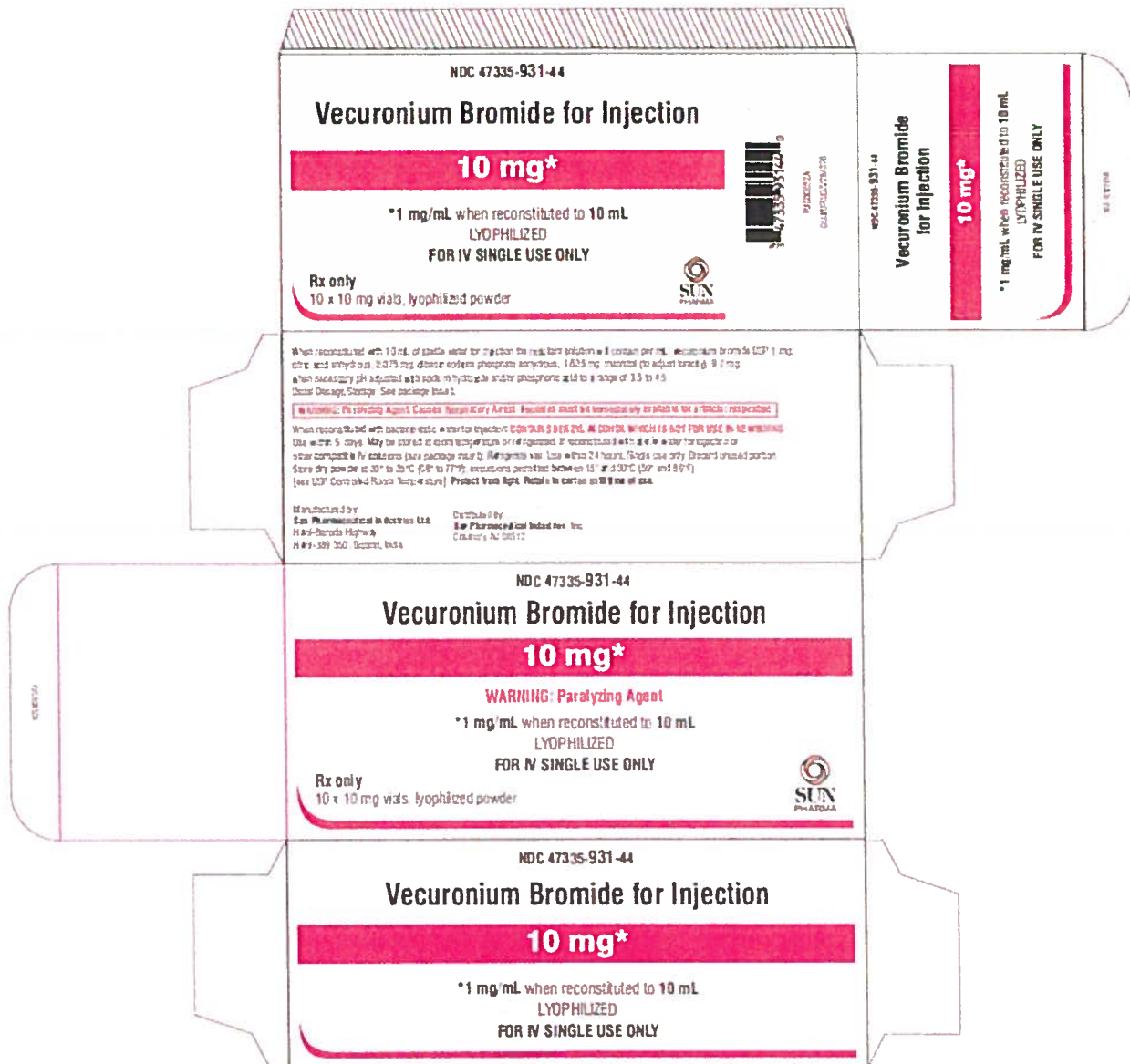
A handwritten signature in blue ink, appearing to read "Kristy Zielny".

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


<p>Rx only 10 x 20 mg vials, lyophilized powder</p> <p>20 mg*</p> <p>*1 mg/mL when reconstituted to 20 mL</p> <p>LYOPHILIZED FOR IV SINGLE USE ONLY</p> <p>Vecuronium Bromide for Injection</p> <p>NDC 47335-932-44</p> <p>ES, IL2016</p>	<p>When reconstituted with 20 mL of sterile water for injection the resulting solution will contain 20 mg/mL vecuronium bromide (USP) 1 mg/mL (0.2075 mg, dibasic sodium phosphate anhydrous, 1.655 mg, included (to adjust tonicity)), 9.7 mg, when necessary, pH adjusted with sodium hydroxide and/or phosphoric acid to a range of 3.5 to 4.5</p> <p>WARNING: Paralyzing Agent. Caution: Respiratory Arrest. Facilities must be immediately available for artificial respiration.</p> <p>When reconstituted with bacteriostatic water for injection, CONTAINS BENZYL ALCOHOL, WHICH IS NOT FOR USE IN NEUROLOGICS. Use within 5 days. May be stored at room temperature or refrigerated.</p> <p>If reconstituted with sterile water for injection or other compatible IV solutions (see package insert C), Refrigera vial. Use within 24 hours. Single use only. Discard unused portion.</p> <p>Store dry powder 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). Protect from light. Retain in carton until time of use.</p> <p>Manufactured by: Sun Pharmaceutical Ind., Ltd. Huda-Banda Highway, Huda-389-350, Gopal, India.</p> <p>Distributed by: Sun Pharmaceutical Industries, Inc. Canbury, NJ 08512</p>
<p>P-550633A</p> <p>Vecuronium Bromide for Injection</p> <p>NDC 47335-932-44</p> <p>20 mg*</p> <p>*1 mg/mL when reconstituted to 20 mL</p> <p>LYOPHILIZED FOR IV SINGLE USE ONLY</p>	<p>Vecuronium Bromide for Injection</p> <p>NDC 47335-932-44</p> <p>20 mg*</p> <p>*1 mg/mL when reconstituted to 20 mL</p> <p>LYOPHILIZED FOR IV SINGLE USE ONLY</p>
<p>Non Varnish Zone</p> <p>Vecuronium Bromide for Injection</p> <p>NDC 47335-932-44</p> <p>20 mg*</p> <p>WARNING: Paralyzing Agent</p> <p>*1 mg/mL when reconstituted to 20 mL</p> <p>LYOPHILIZED FOR IV SINGLE USE ONLY</p> <p>Rx only 10 x 20 mg vials, lyophilized powder</p>	
<p>ES, IL2016</p> <p>47335-93244-7</p> <p>GULPHAS08036 P35053A</p>	



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

Usual Dosage/Storage: See package insert.	NDC 47335-931-40	WARNING: Paralyzing Agent Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.	
CHECK APPROPRIATE BOX	Vecuronium Bromide for Injection	PJLB2392A GUJ/DRUGS/28/396	
<input type="checkbox"/> Reconstituted with bacteriostatic water for injection. CONTAINS BENZYL ALCOHOL, NOT FOR USE IN NEWBORNS. Use within 5 days of.	10 mg*	Batch No.:	
Date Prepared: _____ Time: _____ OR <input type="checkbox"/> Reconstituted with sterile water for injection or compatible IV solutions (per package insert). Single use only. Discard unused portion within 24 hours of.	WARNING: Paralyzing Agent FOR IV USE ONLY	Exp.:	
Date Prepared: _____ Time: _____ Protect from light.	*1 mg/mL when reconstituted to 10 mL.		
Mfg. by: Sun Pharmaceutical Ind. Ltd., India. Dist. by: Sun Pharmaceutical Ind., Inc., NJ 08512	Rx only		

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

Usual Dosage/Storage: See package insert.	NDC 47335-932-40	WARNING: Paralyzing Agent Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.	
CHECK APPROPRIATE BOX	Vecuronium Bromide for Injection	Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512	
<input type="checkbox"/> Reconstituted with bacteriostatic water for injection. CONTAINS BENZYL ALCOHOL, NOT FOR USE IN NEWBORNS. Use within 5 days of.	20 mg*	PJLB2393A	
Date Prepared: _____ Time: _____ OR <input type="checkbox"/> Reconstituted with sterile water for injection or compatible IV solutions (per package insert). Single use only. Discard unused portion within 24 hours of.	WARNING: Paralyzing Agent FOR IV USE ONLY	GUJ/DRUGS/28/396	
Date Prepared: _____ Time: _____ Protect from light.	*1 mg/mL when reconstituted to 20 mL.	Batch No.:	
Manufactured by: Sun Pharmaceutical Ind. Ltd. Halo-Baroda Highway, Halo-389-350, Gujarat, India.	Rx only	Exp.:	



URGENT: DRUG RECALL – RESPONSE FORM

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

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

- | | |
|---|--|
| <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 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
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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: Format:

- 1)
- 2)
- 3) Payment/Credit Summary (if applicable)

4)

5)

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: *Amel Othman* Date: *01-02-19*

Form Received by: _____ Date: _____

Procedures Implemented by: _____ Date: _____

Recall Closed by: _____ Date: _____