



URGENT: DRUG RECALL

Hindy Schiff
Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
135 US Highway 202-206, Suite 15
Bedminster, NJ, 07921

July 9, 2025

Dear Customer:

This is to inform you of a product recall involving Rizatriptan Benzoate Tablets USP, 5 mg and 10 mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed (in cartons of 3x6 blister packs)
1	Rizatriptan Benzoate Tablets USP	22143653	10 mg	July 2025	3 X 6's (Blister Pack)	67877-262-18	December 8, 2022	74,208
2	Rizatriptan Benzoate Tablets USP	22143675	10 mg	July 2025	3 X 6's (Blister Pack)	67877-262-18	January 3, 2023	78,624
3	Rizatriptan Benzoate Tablets USP	22144528	10 mg	September 2025	3 X 6's (Blister Pack)	67877-262-18	March 24, 2023	75,888
4	Rizatriptan Benzoate Tablets USP	22144977	10 mg	November 2025	3 X 6's (Blister Pack)	67877-262-18	May 12, 2023	78,048
5	Rizatriptan Benzoate Tablets USP	23140257	10 mg	December 2025	3 X 6's (Blister Pack)	67877-262-18	July 3, 2023	76,704
6	Rizatriptan Benzoate Tablets USP	23140999	10 mg	February 2026	3 X 6's (Blister Pack)	67877-262-18	August 11, 2023	77,904
7	Rizatriptan Benzoate Tablets USP	23141900	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	October 4, 2023	75,840
8	Rizatriptan Benzoate Tablets USP	23142118	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	November 20, 2023	64,464
9	Rizatriptan Benzoate Tablets USP	23142120	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	January 18, 2024	66,192
10	Rizatriptan Benzoate Tablets USP	23142123	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	February 15, 2024	66,624
11	Rizatriptan Benzoate Tablets USP	23144563	10 mg	November 2026	3 X 6's (Blister Pack)	67877-262-18	May 2, 2024	76,320

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www.ascendlaboratories.com

12	Rizatriptan Benzoate Tablets USP	23144565	10 mg	November 2026	3 X 6's (Blister Pack)	67877-262-18	April 16, 2024	80,400
13	Rizatriptan Benzoate Tablets USP	24142623	10 mg	May 2027	3 X 6's (Blister Pack)	67877-262-18	September 11, 2024	76,416
14	Rizatriptan Benzoate Tablets USP	24142624	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	September 13, 2024	69,072
15	Rizatriptan Benzoate Tablets USP	24142626	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	October 18, 2024	58,944
16	Rizatriptan Benzoate Tablets USP	24143469	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	January 2, 2025	14,112
17	Rizatriptan Benzoate Tablets USP	23142122	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	May 10, 2024	24,912
18	Rizatriptan Benzoate Tablets USP	23142117	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	October 19, 2023	24,912
19	Rizatriptan Benzoate Tablets USP	23142119	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	January 25, 2024	25,344
20	Rizatriptan Benzoate Tablets USP	24142625	5 mg	June 2027	3 X 6's (Blister Pack)	67877-261-18	October 16, 2024	22,560
Total Distributed								1,207,536

See enclosed product labels for ease in identifying the product at the RETAIL level.

An out-of-specification (OOS) result was observed during the analysis of Rizatriptan Benzoate Tablets USP, 5 mg and 10 mg. The observed level of the N-nitroso-dimethyl-rizatriptan impurity was found to exceed the specified limit. Rizatriptan has a tendency to undergo oxidization, which may contribute to the increase of nitrosamine impurity levels during long term stability testing. As a precautionary measure, batches resulting in OOS along with all other non-expired batches are being recalled from the market.

Rizatriptan Benzoate Tablets are prescribed to treat acute migraines. The drug works by constricting blood vessels in the brain, preventing pain signals from reaching the brain and resulting in the inhibition of natural substances that trigger pain, nausea, and other symptoms associated with migraines. Rizatriptan is meant to be used only when needed.

Our firm began shipping this product on October 18, 2022. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above.

Please perform the following activities:

- Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.
- Promptly complete the attached recall stock response form even if you have no product to return.

c. The completed Recall Response Form can be submitted by any of the following methods:

Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent consumer harm.

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a week—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 877-715-3705—available 9:00 AM to 5:00 PM ET Monday through Friday.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Hindy Schiff', with a large, stylized initial 'H'.

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

RECALL STOCK RESPONSE FORM

Recall: Rizatriptan Benzoate Tablets USP, 5 mg and 10 mg

Lots: 22143653, 22143675, 22144528, 22144977, 23140257, 23140999, 23141900, 23142118, 23142120, 23142123, 23144563, 23144565, 24142623, 24142624, 24142626, 24143469, 23142122, 23142117, 23142119, 24142625

Customer Name: _____ DEA #: _____

***Please note that DEA # is required. If it is not provided, the processing of your form will be delayed. ***

Address: _____

City: _____ State: _____ Zip Code: _____

Contact Name (please print): _____ Telephone #: _____

Contact Signature: _____ Date: _____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____ Wholesaler DEA#: _____

Wholesaler City: _____ Wholesaler State: _____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- ☐ I have read and understand the recall instructions provided in the Recall Letter.
- ☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand (in Cartons of 3x6 blisters)
1	Rizatriptan Benzoate Tablets USP	22143653	10 mg	July 2025	3 X 6's (Blister Pack)	67877-262-18	
2	Rizatriptan Benzoate Tablets USP	22143675	10 mg	July 2025	3 X 6's (Blister Pack)	67877-262-18	
3	Rizatriptan Benzoate Tablets USP	22144528	10 mg	September 2025	3 X 6's (Blister Pack)	67877-262-18	
4	Rizatriptan Benzoate Tablets USP	22144977	10 mg	November 2025	3 X 6's (Blister Pack)	67877-262-18	
5	Rizatriptan Benzoate Tablets USP	23140257	10 mg	December 2025	3 X 6's (Blister Pack)	67877-262-18	

6	Rizatriptan Benzoate Tablets USP	23140999	10 mg	February 2026	3 X 6's (Blister Pack)	67877-262-18	
7	Rizatriptan Benzoate Tablets USP	23141900	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	
8	Rizatriptan Benzoate Tablets USP	23142118	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	
9	Rizatriptan Benzoate Tablets USP	23142120	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	
10	Rizatriptan Benzoate Tablets USP	23142123	10 mg	May 2026	3 X 6's (Blister Pack)	67877-262-18	
11	Rizatriptan Benzoate Tablets USP	23144563	10 mg	November 2026	3 X 6's (Blister Pack)	67877-262-18	
12	Rizatriptan Benzoate Tablets USP	23144565	10 mg	November 2026	3 X 6's (Blister Pack)	67877-262-18	
13	Rizatriptan Benzoate Tablets USP	24142623	10 mg	May 2027	3 X 6's (Blister Pack)	67877-262-18	
14	Rizatriptan Benzoate Tablets USP	24142624	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	
15	Rizatriptan Benzoate Tablets USP	24142626	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	
16	Rizatriptan Benzoate Tablets USP	24143469	10 mg	June 2027	3 X 6's (Blister Pack)	67877-262-18	
17	Rizatriptan Benzoate Tablets USP	23142122	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	
18	Rizatriptan Benzoate Tablets USP	23142117	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	
19	Rizatriptan Benzoate Tablets USP	23142119	5 mg	May 2026	3 X 6's (Blister Pack)	67877-261-18	
20	Rizatriptan Benzoate Tablets USP	24142625	5 mg	June 2027	3 X 6's (Blister Pack)	67877-261-18	
Total Product							

☐ Indicate disposition of recall product:

○ Returned/Held for Return (Yes / No)

▪ Quantity: _____

▪ Date: _____

▪ Method: _____

OR

- No recall product on hand (Yes / No)
- ☐ I have identified and notified my customers that this product was shipped/received or may have been shipped by:
 - Date: _____
 - Method of Notification: _____

Were there any adverse events associated with the recalled product?

- ☐ Yes
- ☐ No

If yes, please explain: _____

If you have any questions regarding this form or product return, please contact Inmar at 1-877-715-3705.
Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.

After receipt of this response form, a return kit will be provided for affected product return to:

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX, 75050

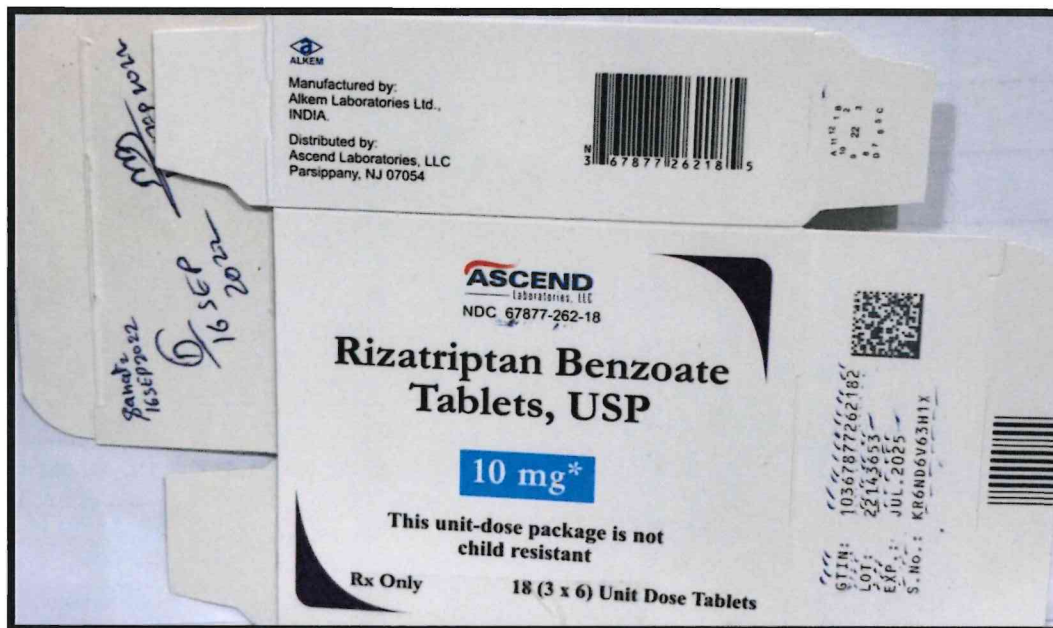
Inmar Recall Event ID: RCL2094-25



ANNEXURE-I (Amended)

PRODUCT IMAGE

Batch # 22143653



Batch # 22143675



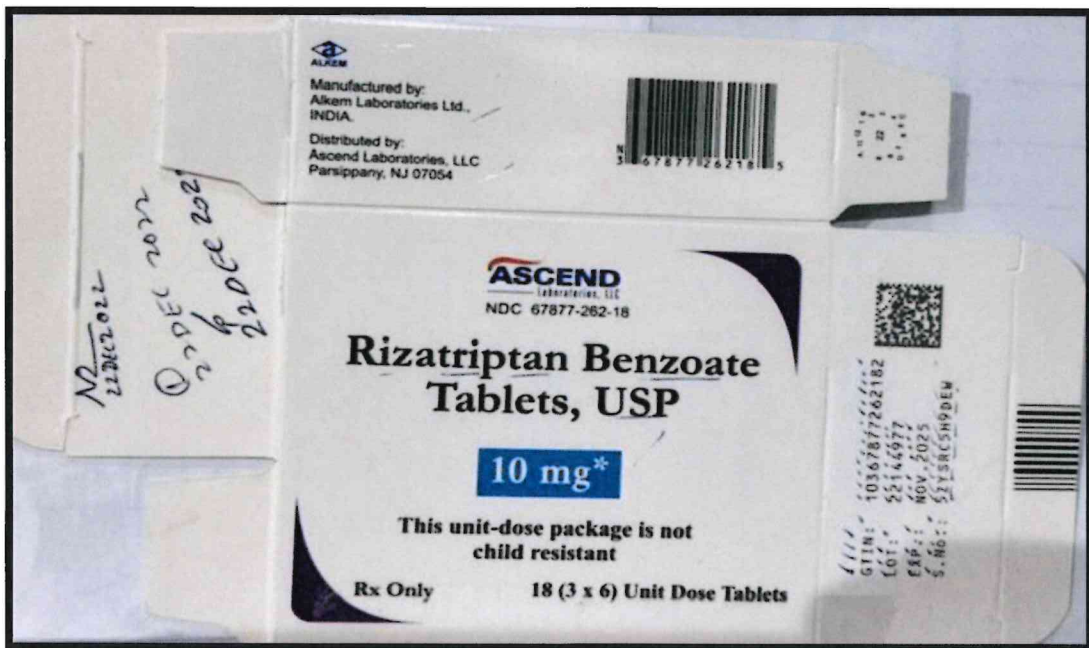


ANNEXURE-I (Amended)

Batch # 22144528



Batch # 22144977



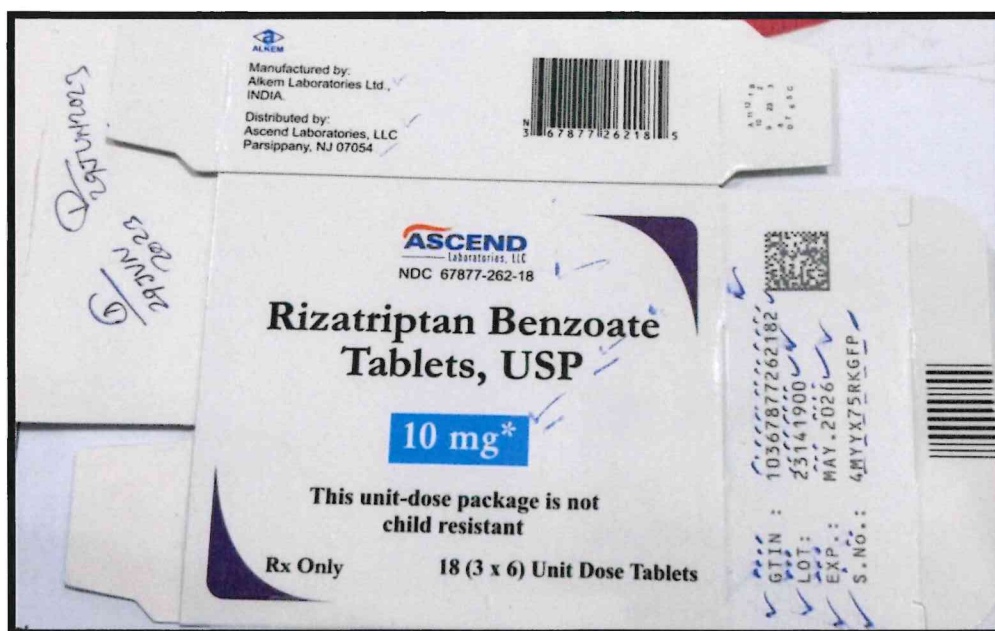


ANNEXURE-I (Amended)

Batch # 23140257



Batch # 23141900



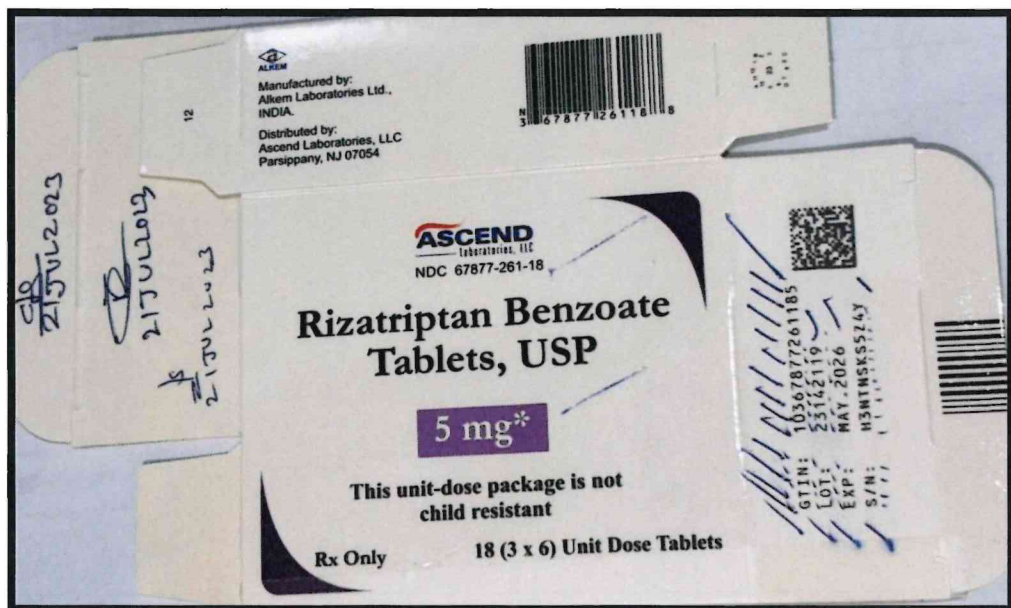


ANNEXURE-I (Amended)

Batch # 23142122



Batch # 23142119



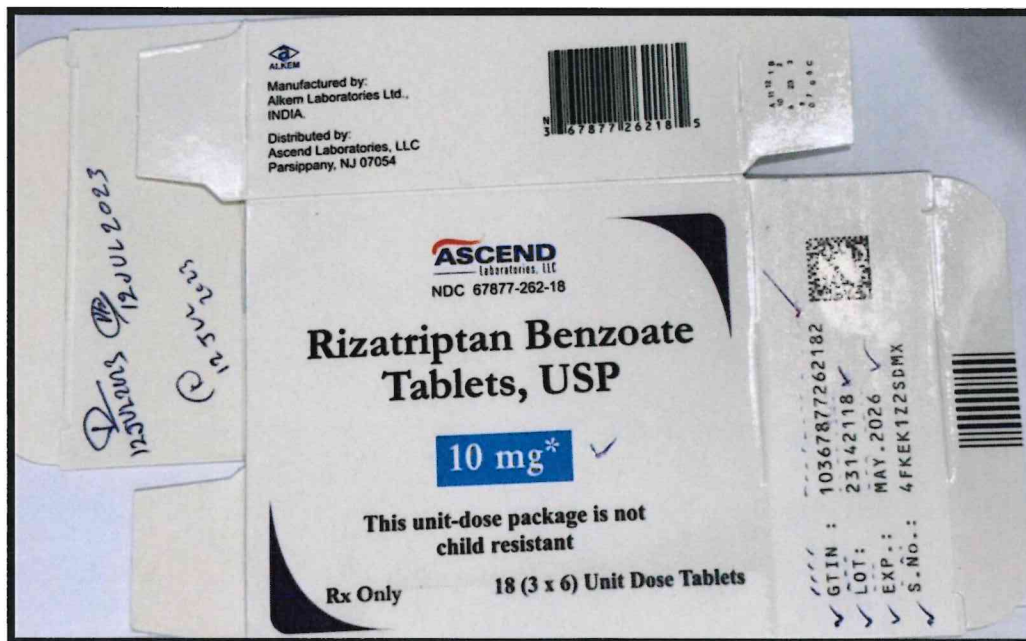


ANNEXURE-I (Amended)

Batch # 23142117



Batch # 23142118





ANNEXURE-I (Amended)

Batch # 23142123



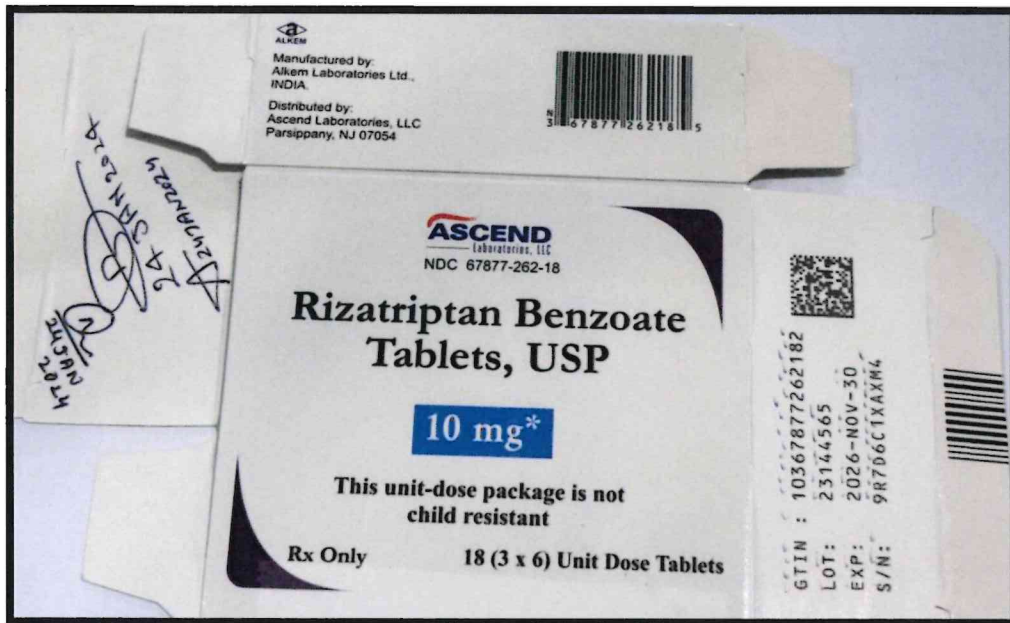
Batch # 23144563





ANNEXURE-I (Amended)

Batch # 23144565



Batch # 24142623





ALKEM

Manufactured by:
Alkem Laboratories Ltd.,
INDIA

Distributed by:
Ascend Laboratories, LLC
Parsippany, NJ 07054

N
3 16 7 8 7 7 0 2 6 2 1 8 5

ASCEND
Laboratories, LLC

NDC 67877-262-18

**Rizatriptan Benzoate
Tablets, USP**

10 mg*

**This unit-dose package is not
child resistant**

Rx Only

18 (3 x 6) Unit Dose Tablets

105565877262182
25 16266
2021-10-50
DHP1C1X1RE
1
6/11/21
Lot:
Exp:
S/N:



ANNEXURE-I (Amended)

Batch # 24142624



Batch # 23142120





ANNEXURE-I (Amended)

Batch # 24140999



Batch # 24143469

