**Rizatriptan Benzoate Tablets 5mg and 10mg; Rizatriptan Benzoate Orally Disintegrating Tablets 5mg and 10mg Class II - Retail Level Recall CUSTOMER CARE TALK TRACK**

**Background Information:** NCQA made an update to their standard requesting communication be sent to members and prescribers affected by any recall classified as a Class II by the FDA except for wholesale level recalls. Communication is being sent to members and prescribers of NCQA delegated clients to inform them of the limited recall. **The manufacturer is not requiring any action on the part of consumers for these recalls.**

**A complete list of the affected products can be found at the end of this document.**

# Customer Care Talk Track:

\*\* Please ensure to disposition all recall calls to code “**1116**” \*\*

|  |  |  |
| --- | --- | --- |
| **Q#** | **Question** | **Answer** |
| **1** | **Why did I receive a recall notice?** | Our records indicate that you may have recently received a prescription for a product affected by a limited recall from your retail pharmacy.  For more information, call the manufacturer listed on the letter or visit their website. You may also call the United States Food and Drug Administration (FDA) toll-free at 1‑888‑INFO-FDA (1‑888-463-6332) or visit [www.fda.gov](http://www.fda.gov). |
| **2** | **May I return the rest of the recalled product that I have?** | The [manufacturer/distributor] is not requiring any action on the part of consumers for these recalls. |
| **3** | **Should I stop using the recalled product?** | Please contact your prescriber with any questions or concerns about this recall or your use of the product. |

|  |  |  |
| --- | --- | --- |
| Product Name | NDC # | Affected Lots |
| Rizatriptan Benzoate 5mg Tablets | 68462-0465-99 | 19233788 exp. 09/2025  19224445 exp. 09/2024 |
| Rizatriptan Benzoate 10 mg Tablets | 68462-0466-99 | 19224217 exp. 09/2024  19233789 exp. 09/2025  19224444 exp. 09/2025 |
| Rizatriptan Benzoate 5mg Orally Disintegrating Tablets | 68462-0467-06 | 19224857 exp. 11/2024  19232493 exp. 06/2025 |
| Rizatriptan Benzoate 10mg Orally Disintegrating Tablets | 68462-0468-06 | 19223402 exp. 07/2024  19224858 exp. 11/2024  19232492 exp. 06/2025 |

Additional Information:

Event Details

**Event ID:**

94606

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

**Initial Firm Notification of Consignee or Public:**

Letter

**Status:**

Ongoing

**Distribution Pattern:**

US Nationwide.

**Recalling Firm:**

Glenmark Pharmaceuticals Inc., USA  
750 Corporate Dr  
Mahwah, NJ 07430-2009  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

5/10/2024

**Center Classification Date:**

6/4/2024

**Date Terminated:**

N/A

**\*N/A -***Not Available*

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Rizatriptan Benzoate Tablets USP, 5mg, 18 (3 X 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 Product of India, NDC 68462-465-99 | D-0532-2024 | Class II | Lot#: 19233788; Exp. 9/2025 Lot#: 19224445; Exp. 9/2024 | 3,480 cartons | CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit. |
| 2 | Rizatriptan Benzoate Tablets USP, 10 mg, 18 (3 X 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 Product of India, NDC 68462-466-99 | D-0533-2024 | Class II | Lot#: 19224217; Exp. 9/2024 Lot#: 19233789; Exp. 9/2025 Lot#: 19224444; Exp. 9/2024 | 11,976 cartons | CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit. |

Update History

**There is no history available for products in this event**

Event Details

**Event ID:**

94608

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

**Initial Firm Notification of Consignee or Public:**

Letter

**Status:**

Ongoing

**Distribution Pattern:**

US Nationwide.

**Recalling Firm:**

Glenmark Pharmaceuticals Inc., USA  
750 Corporate Dr  
Mahwah, NJ 07430-2009  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

5/13/2024

**Center Classification Date:**

6/4/2024

**Date Terminated:**

N/A

**\*N/A -***Not Available*

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Rizatriptan Benzoate Orally Disintegrating Tablets, USP 5mg, 18 (3 x 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-467-06 | D-0534-2024 | Class II | Lot#: 19224857; Exp. 11/2024 Lot#: 19232493; Exp. 6/2025 | 12,574 cartons | CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit. |
| 2 | Rizatriptan Benzoate Orally Disintegrating Tablets, USP 10mg, 18 (3 x 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-468-06 | D-0535-2024 | Class II | Lot#: 19223402; Exp. 6/2024 Lot#: 19224858; Exp. 11/2024 Lot#: 19232492; Exp. 6/2025 | 25,904 cartons | CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit. |

Update History

**There is no history available for products in this event**

[Top of the Document](#_top)

Not To Be Reproduced Or Disclosed to Others Without Prior Written Approval

**ELECTRONIC DATA = OFFICIAL VERSION / PAPER COPY = INFORMATIONAL ONLY**