

## COMPANY ANNOUNCEMENT

# Glenmark Pharmaceuticals Inc., USA Voluntarily Recalls All Unexpired Lots of its Ranitidine Tablets and Ceases Distribution, Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

December 17, 2019

**FDA Publish Date:**

December 17, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

NDMA (Nitrosodimethylamine) impurity

**Company Name:**

Glenmark Pharmaceuticals, Inc.

**Brand Name:**

Glenmark

**Product Description:**

Ranitidine Tablets 150mg and 300mg

## Company Announcement

Glenmark Pharmaceutical Inc., USA (“Glenmark”) today announced the voluntary recall of all unexpired lots of Ranitidine Tablets, 150 mg and 300 mg, to the consumer level.

The recalled lots of Ranitidine Tablets 150 mg and 300 mg, which are listed in Attachment B, are being recalled because of the presence or potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA, based on FDA-validated tests. To date, Glenmark has not received any reports of adverse events that have been confirmed to be directly related to this recall.

**Risk Statement:** NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant typically found in water and foods, including meats, dairy products and vegetables.

Glenmark's Ranitidine Tablets 150 mg and 300 mg are manufactured at two approved manufacturing facilities. Of the 928 recalled lots of Ranitidine Tablets, USP, 16 lots were manufactured by Glenmark Pharmaceuticals Ltd., Goa, India and 912 lots were manufactured by Strides Pharma Science Limited, Puducherry, India. Ranitidine Tablets 150 mg and 300 mg is a prescription oral product approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

Glenmark is committed to product and consumer safety. It will continue to fully cooperate with the FDA as the agency evaluates ranitidine products for the presence of NDMA above established limits and formulates guidance for ranitidine manufacturers. As a further precautionary measure, Glenmark ceased distribution of its Ranitidine products in the United States while it continues its efforts to test and investigate in cooperation with the FDA.

To date, Glenmark has not received any reports of adverse events that have been confirmed to be directly related to this recall. The Ranitidine Tablets, USP, distributed by Glenmark are prescription oral products. Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the stomach. Prescription ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

The Ranitidine Tablets, USP subject to the recall can be identified by the NDC number on the product label. The following NDCs of Ranitidine Tablets, USP, 150 mg and 300 mg, are included in this recall:


NDC	Description	Expiration Date Range
684620-248-60; 684620-248-01 and 684620-248-05	Ranitidine Tablets, USP 150mg	12/2019 – 5/2022

NDC	Description	Expiration Date Range
684620-249-30; 684620-249-01 and 684620-249-20	Ranitidine Tablets, USP 300 mg	12/2019 – 6/2022

The affected Ranitidine Tablets were distributed directly to Wholesalers, Distributors, Retailers and Repackagers nationwide.

The 150mg products product are packaged in bottle packs of 60's, 100's and 500's, whereas, the 300mg products are packaged in bottle packs of 30's, 100's and 250's. Photos are attached below.

Glenmark is notifying its direct customers by mailing (UPS Overnight) a recall notification letter and is arranging for return of all recalled product. Anyone with an existing inventory of the product should quarantine the recalled lot immediately.

Customers who purchased the impacted product directly from Glenmark and consumers can call Qualanex at 1-888-504-2012  Monday – Friday, 9:00 am – 5:00 pm, EST to arrange for product return.

Consumers who have Ranitidine Tablets, USP subject to this recall **should immediately discontinue use and consult with their physician or healthcare provider about treatment options.**

Consumers who would like to report any adverse reactions or quality problems experienced as a result of their use of this product, or have questions regarding the use of Ranitidine Tablets, USP can contact Glenmark Drug Safety by phone at Glenmark customer service center at 1-888-721-7115, Monday thru Friday, 9:00 am – 6:00 pm, US EST, or e-mail at [GlobalCustomerService@glenmarkpharma.com](mailto:GlobalCustomerService@glenmarkpharma.com).

(<mailto:GlobalCustomerService@glenmarkpharma.com>) Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to the use of this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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## Company Contact Information

### Consumers:

Glenmark Drug Safety

☎ 1-888-721-7115

✉ GlobalCustomerService@glenmarkpharma.com (mailto:GlobalCustomerService@glenmarkpharma.com)

# Product Photos



**NDC 68462-248-05**

# Ranitidine Tablets USP

**150 mg**



**Rx Only 500 Tablets**

Each tablet contains 150 mg of ranitidine as ranitidine hydrochloride USP.

See package insert for Dosage and Administration.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light. Replace cap securely after each opening.

Manufactured by: Glenmark Pharmaceuticals Ltd. Coivale-Barddez, Goa 403513, India


Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

GO/RUGS/648 09/17



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Questions? 1 (888)721-7115 www.glenmarkpharma.com/usa

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**NDC 68462-249-30**

# RANITIDINE TABLETS USP

**300 mg**

**Rx Only 30 Tablets**

Each tablet contains 300 mg of ranitidine as ranitidine hydrochloride USP.

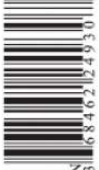
See package insert for Dosage and Administration.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light. Replace cap securely after each opening.


Manufactured by: Sirdes Shasun Limited Unit-II, R.S.No. 32, 33 & 34, PIMS Road, Periyakattai, Puducherry - 605 014, India. Mfg. Lic. No. 16 13 4193

Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430


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