

# Amneal Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Nizatidine Oral Solution, 15 mg/mL, Due to Potential Levels of NDMA Impurity Amounts Above the Levels Established by FDA

FDA Publish Date: 4/15/2020

Amneal Pharmaceuticals, LLC, Bridgewater, New Jersey is voluntarily recalling three lots of Nizatidine Oral Solution, 15 mg/mL (75 mg/5mL), packaged in 480 mL bottles to the Consumer Level. Nizatidine Oral Solution was distributed by Gemini Laboratories, LLC, a wholly owned subsidiary of Amneal Pharmaceuticals. The three recalled lots are identified in the table below. Nizatidine Oral Solution is being recalled due to potential N-Nitrosodimethylamine (NDMA) amounts exceeding the levels established by the FDA.

**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 and found in water and foods, including meats, dairy products, and vegetables.

Amneal Pharmaceuticals, LLC has not received any reports of adverse events that have been confirmed to be directly related to this recall. Nizatidine Oral Solution manufactured by Amneal, is a prescription oral product used for the short-term treatment and maintenance therapy of ulcers and for the treatment of esophagitis and associated heartburn due to gastroesophageal reflux disease (GERD).

The Nizatidine Oral Solution lots subject to the recall can be identified by the NDC number and lot number listed on the product label:

NDC No.	Description	Lot	Expiration Date
60846-0301-15	Nizatidine Oral Solution	06598004A	04/2020
60846-0301-15	Nizatidine Oral Solution	06599001A	12/2020
60846-0301-15	Nizatidine Oral Solution	06599002A	12/2020

The affected Nizatidine Oral Solution lots were distributed directly to wholesalers who further distributed to retail pharmacies and consumers nationwide in the USA.

Amneal is notifying its direct customers by mailing (FED Ex Standard 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 lots immediately.

Customers who purchased the impacted product directly from Amneal can call Inmar at (855) 319-4807, Monday – Friday, 8:00 am – 6:00 pm, EST, or e-mail at [DrugSafety@amneal.com](mailto:DrugSafety@amneal.com) for further information. Consumers should contact their physician or other healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Consumers who have Nizatidine Oral Solution which is being recalled should stop using the product and can call Inmar at 855-319-4807, Monday – Friday, 8:00 am – 5:00 pm, EST for further information.

Consumers who would like to report adverse reactions or quality problems experienced with the use of this product can contact Amneal Drug Safety by phone at 1-877-835-5472, Monday thru Friday, 8:00 am – 6:00 pm, EST, or e-mail at [DrugSafety@amneal.com](mailto:DrugSafety@amneal.com).

Consumers should 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.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Link to FDA website: [Link](#)

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## Company Contact Information

### Consumers:

Inmar  
855-319-4807  
[DrugSafety@amneal.com](mailto:DrugSafety@amneal.com)

### Media:

Ms. Candis Edwards  
[Information@amneal.com](mailto:Information@amneal.com)


Product Photos

NDC 60846-301-15  
**NIZATIDINE  
ORAL SOLUTION**  
15 mg/mL (75 mg/5 mL)  
Each mL contains 15 mg of  
nizatidine.

**Rx only** 480 mL

Distributed by:  
Gemini Laboratories, LLC  
Bridgewater, NJ 08807

Rev. 07-2016-01



NDC 60846-301-15  
**NIZATIDINE  
ORAL SOLUTION**

**15 mg/mL (75 mg/5 mL)**

Each mL contains 15 mg of nizatidine.

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].

**KEEP THIS AND ALL DRUGS OUT OF THE REACH  
OF CHILDREN**

Dispense in a light, light-resistant container as  
defined in the USP.

**GEMINI  
LABORATORIES**

**Rx only**  
480 mL