COMPANY ANNOUNCEMENT

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

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:

April 15, 2020

FDA Publish Date:

April 15, 2020

Product Type:

Drugs

Reason for Announcement:

NDMA (Nitrosodimethylamine) impurity

Company Name:

Amneal Pharmaceuticals, LLC

Brand Name:

Gemini Laboratories

Product Description:

Nizatidine Oral Solution 15 mg/mL

Company Announcement

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
60846-301-15	Nizatidine Oral Solution	06598004A	04/2020
60846-301-15	Nizatidine Oral Solution	06599001A	12/2020
60846-301-15	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.

Amnealis 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 (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 (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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

Safe Harbor Statement

Certain statements contained herein, regarding matters that are not historical facts, may be forward-looking statements (as defined in the Private Securities Litigation Reform Act of 1995). Such forward-looking statements include statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, including, among other things, future operating results and financial performance, product development and launches, integration strategies and resulting cost reduction, market position and business strategy. Words such as “may,” “will,” “could,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “assume,” “continue,” and similar words are intended to identify estimates and forward-looking statements.

The reader is cautioned not to rely on these forward-looking statements. These forward-looking statements are based on current expectations of future events. If the underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Amneal Pharmaceuticals, Inc. (the “Company”). Such risks and uncertainties include, but are not limited to, risks related to the products and recall thereof described in this press release. A further list and descriptions of these risks, uncertainties and other factors can be found in the Company’s most recently filed

Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as supplemented by any subsequently filed Quarterly Reports on Form 10-Q. Copies of these filings are available online at www.sec.gov, www.amneal.com or on request from the Company.

Company Contact Information

Consumers:

Inmar

855-319-4807

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Media:

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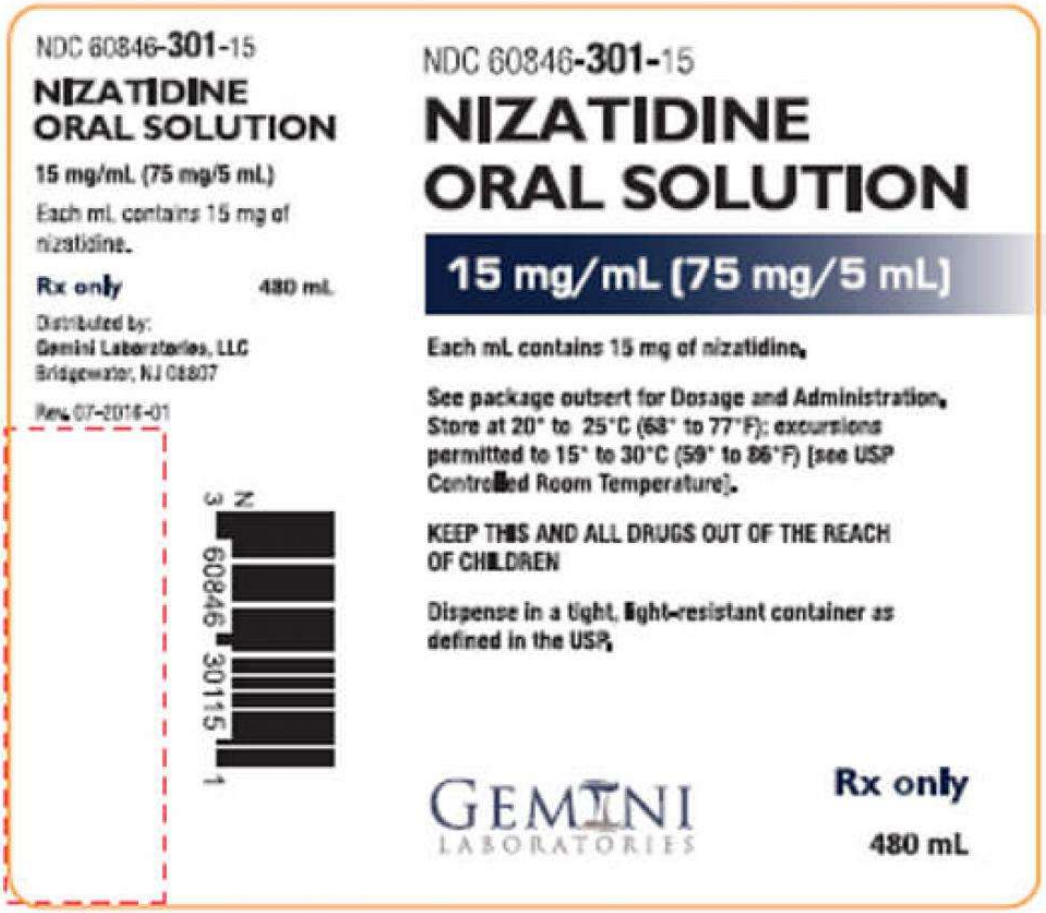
Product Photos



More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)