

This notice is to inform you that on April 15th, 2020 the U.S. Food and Drug Administration (FDA) announced that Amneal Pharmaceuticals, Inc. is voluntarily recalling three (3) lots of Nizatidine Oral Solution, 15mg/mL due to potential N-Nitrosodimethylamine (NDMA) amounts exceeding the levels established by the FDA.

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 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

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 should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of this drug product.