Nizatidine Oral Solution 15 mg/mL

Date: 4/15/2020

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Amneal Pharmaceuticals has posted a lot recall of Nizatidine Oral Solution 15 mg/mL.

About this Recall:
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 FDA Recall Notification link below. Nizatidine Oral Solution is being recalled due to potential N-Nitrosodimethylamine (NDMA) amounts exceeding the levels established by the FDA.

What this means to you:
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 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.

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.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-nizatidine-oral-solution-15-mgml-due

FDA contact information for reporting adverse events/quality complaints can be reached online at
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2