RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Nizatidine Oral Solution 15mg/ml Recall Alert

Date of Notice: 04/15/2020

Brief Description of Recall

On April 15, 2020, Amneal Pharmaceuticals, LLC is voluntarily recalling three lots of nizatidine oral solution, 15mg/ml (75mg/5ml). The product is being recalled 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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Nizatidine oral solution, 15mg/ml	60846-301-15	06598004A	04/2020
		06599001A 06599002A	12/2020

Prescriber Information

Amneal Pharmaceuticals, LLC has not received any reports of adverse events that have been confirmed to be directly related to this recall.

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

Member Information

Members who purchased the impacted drug 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.

Members should contact their prescriber if they have experienced any problems that may be related to taking or using this drug product.

Members who have nizatidine oral solution which is being recalled should stop using the drug and call Inmar at 855-319-4807, Monday – Friday, 8:00 am – 5:00 pm, EST for further information.

Members 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.

Members should contact their prescriber if they have experienced any problems that may be related to the use of this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.