RXADVANCE
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Nizatidine capsules Recall Alert

Date of Notice: 01/08/2020

Brief Description of Recall

On January 8, 2020, Mylan Pharmaceuticals issued a voluntary recall of three lots of nizatidine capsules, 150mg and 300mg strengths, due to detected trace amounts of N-nitrosodimethylamine (NDMA).

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 150mg capsules	0378-5150-91	3086746	05/2020
nizatidine 300mg capsules	0378-5300-93	3082876 3082877	01/2020

Prescriber Information

Mylan has not received any reports of adverse events related to these batches to date.

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 that are in possession of recalled drug should contact Stericycle at 888-628-0727 for the return of the recalled drug. Normal business hours are Monday through Friday 8 a.m. to 5 p.m. EST.

Members should contact their prescriber if they have experienced any problems that may be related to using these drug products.

RxAdvance Response

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