RXADVANCE
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Southborough, MA 01772

Ranitidine tablets Recall Alert

Date of Notice: 01/06/2020

Brief Description of Recall

On January 6, 2020, Denton Pharma, Inc. dba Northwind Pharmaceuticals issued a voluntary recall of all unexpired lots of ranitidine tablets due to the presence 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
ranitidine tablets, USP 150mg	70934-017-04 70934-017-20 70934-017-24 70934-017-30 70934-017-90	All lots	All dates
ranitidine tablets, USP 300mg	70934-287-15 70934-287-90	All lots	All dates

Prescriber Information

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 Northwind can call Northwind at 1-800-722-0772 Monday – Friday, 9:00 am – 5:00 pm, EST to arrange for product return.

Members who have ranitidine tablets subject to this recall should immediately discontinue use, discard remaining drug, and consult with their prescriber about treatment options.

Members who would like to report any adverse reactions or quality problems experienced as a result of their use of this product, or who have questions regarding the use of ranitidine tablets, can contact Northwind at 1-800-722-0772 Monday – Friday, 9:00 am – 5:00 pm, EST.

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

RxAdvance Response

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