RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Ranitidine capsules Withdrawal Alert

Date of Notice: 04/17/2020

Brief Description of Withdrawal Alert

On April 17, 2020, Strides Pharma, Inc. has issued a voluntary withdrawal of ranitidine capsules from the market immediately. The FDA has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures may result in consumer exposure to unacceptable levels of this 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 oral capsules, 150mg	27241-0109-06 27241-0109-50	All lots	All dates
ranitidine oral capsules, 300mg	27241-0110-03 27241-0110-10	All lots	All dates

Prescriber Information

To date, the FDA's testing has not found NMDA in famotidine, cimetidine, esomeprazole, lansoprazole or omeprazole.

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 should stop taking the drug and talk to your prescriber about alternative treatments. For more information about this withdrawal, please call Strides Pharma Inc. at 1-877-861-3811.

RxAdvance Response

RxAdvance is in the process of notifying members who have recently filled a prescription for this drug.