RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Ranitidine (Zantac and generics) Withdrawal Alert

Date of Notice: 04/01/2020

Brief Description of Withdrawal Alert

On April 1, 2020, the FDA has requested manufacturers to withdraw ranitidine, all dosage forms and strengths from the market immediately. 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 capsules, 150mg and 300mg	All NDCs	All lots	All dates
ranitidine injection, 50mg/2ml	All NDCs	All lots	All dates
ranitidine oral syrup, 15mg/ml	All NDCs	All lots	All dates
ranitidine tablets (prescription and OTC) 75mg, 150mg and 300mg	All NDCs	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.

RXADVANCE
2 Park Central Drive
Southborough, MA 01772

RxAdvance Response

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