

## Ranitidine syrup Withdrawal Alert

Date of Notice: 04/07/2020

### Brief Description of Withdrawal Alert

On April 7, 2020, Pharmaceutical Associates, Inc. has issued a voluntary withdrawal of ranitidine oral syrup 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 syrup | 00121-0727-16<br>00121-4727-10 | All lots | All dates       |

### Prescriber Information

To date, the FDA's testing has not found NDMA 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, please contact Pharmaceutical Associates, Inc. at 1-877-993-8779, Monday through Friday, 9:00am to 5:00pm EST.

### RxAdvance Response

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

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