

ISSUE: The FDA announced it is requesting manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately.

This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). NDMA is a probable human carcinogen (a substance that could cause cancer). 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 impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

BACKGROUND: Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the stomach. Prescription ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

RECOMMENDATION:

- **Consumers:** The FDA is also advising consumers taking OTC ranitidine to stop taking any tablets or liquid they currently have, dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products.
- **Patients:** Patients taking prescription ranitidine should speak with their health care professional about other treatment options before stopping the medicine, as there are multiple drugs approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. To date, the FDA's testing has not found NDMA in famotidine (Pepcid), cimetidine (Tagamet), esomeprazole (Nexium), lansoprazole (Prevacid) or omeprazole (Prilosec).
- **Consumers and Patients:** In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the FDA's recommended [steps](#) which include ways to safely dispose of these medications at home.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the [report online](#).
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form or submit by fax to 1-800-FDA-0178.