



Ongoing ranitidine recalls

To assist you in the care of your patients, we want to alert you to the ongoing recall of ranitidine products.¹ We recommend you review your medical records and contact all patients for whom you have prescribed ranitidine to warn them of the recall. We have listed alternative options below.

CarePlus anticipates the recalls will continue. Monitor the FDA's website for the most up-to-date ranitidine recall information: www.FDA.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

Recommendations:

Preferred formulary alternatives:

Recalled medication	Preferred alternative
ranitidine	omeprazole capsules
	pantoprazole tablets
	famotidine oral suspension
	cimetidine oral solution

To access CarePlus' formulary drug list search, go to:

www.CarePlusHealthPlans.com/medicare-plans/2020-prescription-drug-guides

Information for patients:¹

- Patients should visit the FDA website or their pharmacy to see the latest ranitidine updates.
- Patients should contact their pharmacists or physicians if 1) their medicine is included in this recall, 2) if they experience any problems related to taking this product and 3) if they wish to stop taking prescription ranitidine. Their physicians or pharmacists can help identify alternate healthcare treatment options. See the above formulary alternative list.
- To determine if a specific product has been recalled, patients should look at the drug name and company name on the label of their prescription package(s). If the information is not on the prescription package, patients should contact the pharmacy that dispensed the medicine.

- 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:
 - **Online:** Complete and submit the report at www.accessdata.fda.gov/scripts/medwatch/
 - Select “Consumer/Patient (FDA Form 3500B).”
 - **Regular mail or fax:** Download form at www.fda.gov/node/360547
 - Select “Form FDA 3500B – Voluntary Reporting for Consumers” and submit by mail to the address on the form or by fax to **1-800-FDA-0178**.

Background:

This recall was initiated because of confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the U.S. Food and Drug Administration (FDA) in batches of ranitidine. NDMA is classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC). While it is found in trace amounts in water and foods—including meats, dairy products and vegetables—the amounts identified in the drug products are at unacceptable levels.

Reference:

1. U.S. Food and Drug Administration. FDA Updates and Press Announcements on NDMA in Zantac (ranitidine). www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine. Accessed Oct. 30, 2019.