The Medical Letter®

on Drugs and Therapeutics

Volume 68 April 13, 2026

ISSUE No. 1752

IN THIS ISSUE

The Medical Letter®
on Drugs and Therapeutics

Volume 68 (Issue1752) April 13, 2026

Take CME Exams

IN BRIEF

Ranitidine Returns

The FDA has approved a new tablet formulation of the H2-receptor antagonist (H2RA) ranitidine from one manufacturer (VKT Pharma/Rising Pharma). It is only available by prescription. In 2020, the FDA requested that all formulations of ranitidine be withdrawn from the market because unacceptable levels of the nitrosamine compound *N*-nitrosodimethylamine (NDMA), a potentially carcinogenic contaminant, had been detected in ranitidine samples.

NDMA — NDMA can be found in drinking water (as a byproduct of water disinfection) and in some processed foods. It has been found in many drugs, including nizatidine, which is structurally related to ranitidine. High levels of NDMA have been shown to induce tumors in multiple organs in animals; it is classified as a probable human carcinogen.

FDA testing found that NDMA levels in the original ranitidine formulations increased over time and when the drug was stored at high temperatures. Approval of the reformulated tablets was based on changes in the manufacturing process that improve the stability of the drug, minimizing formation of NDMA during its shelf life.

Table 1. Storage and Handling of Ranitidine Tablets

- Dispense and keep tablets in the original bottle with the desiccant.
- If more than one bottle is dispensed, open only one bottle at a time. Store additional bottles without opening until needed for dosing.
- At the time of dosing, remove one tablet from the bottle. Immediately close the bottle, secure the cap, and keep the bottle tightly closed to protect from moisture.
- Discard unused tablets 3 months (90 days) after first opening the bottle or by the expiration date on the bottle, whichever is sooner.

AVAILABILITY — Prior to removal, ranitidine was available over the counter (OTC) and by prescription (*Zantac,* and generics).[1] The active ingredient in OTC *Zantac 360* is now the H2RA famotidine (see Table 2).

The new formulation is available by prescription in bottles of 30 tablets containing either 150 mg or 300 mg of ranitidine. The bottles should be stored at 15-30°C (59-86°F) in a dry place and protected from light. The updated label states that the tablets must be dispensed in the original container. The label also includes storage and handling instructions for patients (see Table 1).

Table 2. H2-Receptor Antagonists

Drug	Oral Formulations	Usual Adult Dosage	Cost[1]
Cimetidine – generic	200, 300, 400, 800 mg tabs; 300 mg/5 mL soln	200-400 mg bid	$18.10
Tagamet HB (OTC)[2] (Medtech)	200 mg tabs		18.00
Famotidine – generic	20, 40 mg tabs; 40 mg/5 mL susp	20-40 mg bid	3.20
Pepcid AC (OTC)[2] (J&J Consumer)	10, 20 mg tabs		18.20[3]
Zantac 360 (OTC)[2] (Chattem)	20 mg tabs		12.50[3]
Nizatidine – generic	150, 300 mg caps; 15 mg/mL soln	150 mg bid	50.00
Ranitidine – generic (VKT Pharma/Rising Pharma)	150, 300 mg tabs	150 mg bid	398.10

OTC = over the counter; soln = solution; susp = suspension
1. Approximate WAC for 30 days' treatment with the lowest usual adult dosage. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. March 5, 2026. Reprinted with permission by First Databank, Inc. All rights reserved. ©2026. www.fdbhealth.com/drug-pricing-policy.
2. Also available generically.
3. Approximate WAC for fifty 20-mg tablets.

FDA GUIDANCE — The FDA recently issued guidance on acceptable intake (AI) limits for NDMA and some other nitrosamine impurities in drugs. The AI represents the level at or below which the impurity would not be considered a safety concern.[2] The updated ranitidine label states that the formulation meets FDA-approved specifications for nitrosamine impurities. ■

1. Drugs for GERD and peptic ulcer disease. Med Lett Drugs Ther 2022; 64:49.
2. FDA. CDER nitrosamine impurity acceptable intake limits. March 19, 2026. Available at: https://bit.ly/4qpMFjQ. Accessed March 26, 2026.