

Apotex – Recall of ranitidine

- On September 26, 2019, the [FDA alerted](#) healthcare providers and patients to a voluntary, **retail level** recall of [Apotex's](#) over-the-counter (OTC) ranitidine tablets labeled by Walgreens, Walmart, and Rite-Aid due to potential contamination with low levels of N-nitrosodimethylamine (NDMA).
- This recall follows a recent [FDA statement](#) about NDMA impurities detected in ranitidine medicines. The FDA also recently alerted patients and healthcare providers of [Sandoz's](#) voluntary, **consumer level** recall of prescription ranitidine capsules due to an NDMA impurity on September 23, 2019.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
- The following recalled OTC ranitidine tablets made by Apotex were distributed nationwide to warehousing chains:

Product Description	NDC#
Ranitidine tablets, 150 mg- acid reducer (Rite Aid)	11822-6052-1
Ranitidine tablets, 150 mg- acid reducer (Rite Aid)	11822-6052-2
Ranitidine tablets, 150 mg- acid reducer (Rite Aid)	11822-4727-3
Ranitidine tablets, 150 mg- acid reducer (Walmart)	49035-117-06
Ranitidine tablets, 150 mg- acid reducer (Walmart)	49035-100-00
Wal-Zan [®] 150 Ranitidine tablets, 150 mg / acid reducer (Walgreens)	0363-1030-07
Ranitidine tablets, 150 mg - acid reducer (Rite Aid)	11822-6051-8
Ranitidine tablets, 150 mg- acid reducer (Walmart)	49035-100-07
Wal-Zan [®] 150 Ranitidine tablets, 150 mg / acid reducer (Walgreens)	0363-1013-02
Wal-Zan [®] 75 Ranitidine tablets, 75 mg / acid reducer (Walgreens)	0363-1029-03
Cool mint Ranitidine tablets, 150 mg - acid reducer (Rite Aid)	11822-6107-4
Wal-Zan [®] 150 Ranitidine tablets, 150 mg / acid reducer (Walgreens)	0363-1030-06
Wal-Zan [®] 150 Ranitidine tablets, 150 mg / acid reducer (Walgreens)	0363-1030-09

- Ranitidine is an OTC and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach. OTC ranitidine is approved to prevent and relieve heartburn associated with acid ingestion and sour 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.
- FDA patient recommendations:
 - Individuals should not stop taking all ranitidine medicines at this time.
 - Consumers taking OTC ranitidine could consider using other OTC products approved for their condition.

- Patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional about other treatment options. Multiple drugs are approved for the same or similar uses as ranitidine.
- FDA healthcare provider recommendations:
 - Multiple drugs are approved for the same or similar uses as ranitidine. Healthcare providers should discuss other treatment options with patients who are concerned about ranitidine.
 - Samples of recalled ranitidine should not be provided to patients.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled ranitidine.
- Anyone with an existing inventory of the recalled product should quarantine the product immediately.
- The FDA is continuing to test ranitidine products from multiple manufacturers and assess the possible effect on patients who have been taking ranitidine. Additionally, the FDA recently posted a testing method, which can be used by regulators and industry to detect nitrosamine impurities in ranitidine. The FDA has asked ranitidine manufacturers to conduct laboratory testing to examine levels of NDMA in ranitidine and to send samples of ranitidine to the agency to be tested by the FDA.
- The FDA will take appropriate measures based on the results of this ongoing investigation. Some manufacturers have chosen to stop distribution of ranitidine as a precautionary measure while the FDA and other international regulators conduct their investigations of the NDMA impurity.
- The FDA continues to evaluate the safety of ranitidine and will provide more information as it becomes available.
- Contact Apotex by phone at **1-800-706-5575** or by email at **UScustomerservice@Apotex.com** for further information regarding this recall.



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