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Immediate Release:
Drug Recall of Ranitidine

On September 13, 2019, the U.S. Food and Drug Administration (FDA) released a statement alerting patients and healthcare professionals that N-nitrosodimethylamine (NDMA), a substance that could cause cancer, was found in samples of over-the-counter and prescription ranitidine medicines.

NDMA is a known environmental contaminant that can be found in water and foods, including meats, dairy products and vegetables. The NDMA contaminant found in ranitidine has also been the source of other medication recalls, such as losartan and valsartan.

Ranitidine decreases the amount of acid created in the stomach and is approved to prevent and relieve heartburn, ulcers of the stomach and intestines as well as the treatment of gastroesophageal reflux disease. Some manufacturers and distributors of ranitidine, such as Walgreens, Walmart, Rite-Aid, Apotex and Sandoz, have chosen to stop the distribution or voluntarily recall ranitidine as a precautionary measure.

While the FDA is working to determine the source of this impurity and evaluating any possible risk to patients, those taking ranitidine can continue to take ranitidine that has not been recalled. The FDA has asked manufacturers of ranitidine to conduct their own laboratory testing to assess levels of NDMA in their ranitidine products and send samples to the FDA for testing.

If a patient is taking one of the recalled medicines, they should follow the recall instructions provided by the company. This information is available on the FDA's website. Patients taking ranitidine who wish to discontinue use should talk to their healthcare professional about other treatment options. The FDA will provide more information as it becomes available.

References

1. Statement alerting patients and health care professionals of NDMA found in samples of ranitidine. FDA Statement. Available at: https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine. Updated September 13, 2019. Accessed October 14, 2019.
2. FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity. FDA News Release. Available at: https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity. Updated September 24, 2019. Accessed October 14, 2019.
3. FDA alerts health care professionals and patients to voluntary recall of ranitidine medicines. FDA Statement. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine. Updated September 26, 2019. Accessed October 14, 2019