DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity

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The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of 14 lots of prescription ranitidine capsules distributed by Sandoz Inc., used to decrease the amount of acid created by the stomach. This recall is due to a nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine. NDMA is classified as a probable human carcinogen (a substance that could cause cancer).

"The FDA is committed to ensuring that the medicines Americans take are safe and effective. We began testing ranitidine products immediately after we learned of the potential impurity. When we identify lapses in the quality of drugs that pose potential risks for patients, the FDA makes all efforts to understand the issue and provide our best recommendation to the public as quickly and accurately as possible," said Acting FDA Commissioner Ned Sharpless, M.D. "We will continue to investigate and work to ensure these types of impurities do not exceed acceptable limits, so that patients can continue taking the medicines they need without concern."

Ranitidine is an over-the-counter (OTC) and prescription drug. Ranitidine is a 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. The agency today provided the following information for patients and health care professionals on the recall of ranitidine capsules produced by Sandoz:

- 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.
- While the FDA investigates the root cause and risk, consumers and patients can continue to take ranitidine that has not been recalled. It is important to remember that not all ranitidine marketed in the U.S. is being recalled.
- 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.
- Consumers taking OTC ranitidine could consider using other OTC products for their condition.

"We are continuing our investigation along with our international counterparts, and we will keep the American public informed of any additional recalls as well as the potential risks from taking ranitidine products," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

The agency is testing ranitidine products from multiple manufacturers and assessing the possible effect on patients who have been taking ranitidine, as well as what manufacturers can do to reduce or eliminate nitrosamine in drugs.

As part of the FDA's investigation, the agency recently posted a testing protocol, which can be used by regulators and industry to detect nitrosamine impurities in ranitidine. The FDA is asking companies to begin their own laboratory testing to examine levels of NDMA in ranitidine and to send samples of ranitidine to the FDA to be tested by agency scientists.

The FDA and manufacturers of ranitidine will take appropriate measures based on the results of this ongoing investigation and the agency will provide additional information when it becomes available. The FDA encourages patients and health care professionals to report any adverse reaction to the agency's MedWatch program.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The affected Sandoz Ranitidine includes 30 count, 60 count and 500 count bottles in the following lots:

Product Name	**NDC Number**	**Lot Nbr.**	**Expiration Date**	**Date of Manufacture**
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HD1862	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9438	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9439	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9440	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HC9266	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HD1865	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HP9441	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK7994	8/31/2021	8/7/2018
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK8659	8/31/2021	8/7/2018

Product Name	NDC Number	Lot Nbr.	Expiration Date	Date of Manufacture
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD8625	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD9275	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HU2207	8/31/2020	8/24/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6676	3/31/2021	3/20/2018
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6677	3/31/2021	3/20/2018

The product can be identified by the NDC number and lot number provided above. Sandoz Ranitidine Hydrochloride Capsules were distributed nationwide to wholesalers.

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Source: https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity