Generic Name:
Ranitidine
Trade Name:
Generic Zantac
Company:
Sandoz
Notes:

FDA is alerting health professionals and patients of a voluntary recall of 14 lots of prescription ranitidine capsules distributed by Sandoz. 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.

Ranitidine is an OTC and prescription drug that prevents and relieves 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 provided the following information for patients and health professionals:

?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 FDA?s website.

?While 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 United States is being recalled.

?Patients taking prescription ranitidine who wish to discontinue use should talk to their health 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.

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.

Medication Monitor Categories:
Alerts and Recalls