

October 2019

## Ranitidine Recall

**The Issue:** Ranitidine is a histamine-2 (H<sub>2</sub>) blocker, which decreases the amount of acid created by the stomach. It is available generically by prescription and over the counter for the short-term treatment of gastroesophageal reflux disease as well as gastric and duodenal ulcers. The Food and Drug Administration (FDA) recently announced voluntary recalls of ranitidine manufactured by 2 pharmaceutical companies:

- ranitidine manufactured by Sandoz which was [recalled on September 23rd, 2019](#) and
- ranitidine manufactured by Apotex which was [recalled on September 25th, 2019](#).

The recalls were issued due to small amounts of an unexpected impurity, a chemical called N-nitrosodimethylamine (NDMA), found in the medications.

**What is NDMA?** NDMA is a chemical that has been classified as a probable human carcinogen based on laboratory test results when ingested in large amounts. Small amounts of NDMA can be found in water and foods (e.g., meats, dairy products and vegetables).

**Are all ranitidine products being recalled?** No. Only ranitidine that is made by Sandoz and Apotex have been recalled. Ranitidine developed by other pharmaceutical companies have not been found to contain NDMA. Some stores and supermarkets have taken all of their ranitidine products off of the shelf even if they aren't part of the recall in an attempt to be extra cautious.

**Can you still purchase ranitidine?** Yes. The ranitidine purchased through McKesson and the National Supply Service Center is available and not included in the recall.

**Should patients stop taking ranitidine?** Patients should continue ranitidine therapy if it remains indicated and if it is not included in the recall. It is always a good idea to re-evaluate the need for continued acid-suppression therapy. Consider discontinuing medication therapy and/or replacing it with non-pharmacological treatments when possible which include;

- Avoiding or limiting triggers that cause GI distress (e.g., spicy foods, tomatoes, chocolate, coffee, alcohol, fatty foods and acidic foods)
- Loosen clothing or avoiding restrictive clothes
- Sitting or standing upright after eating
- Chewing sugarless gum
- Eating smaller meals
- Reviewing medication lists to identify medications contributing to GI distress