Ranitidine – Safety alert

- On September 13, 2019, the FDA announced that some ranitidine medicines contain the nitrosamine impurity, N-nitrosodimethylamine (NDMA), at low levels.
    - 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 FDA is not calling for individuals to stop taking ranitidine at this time; however, patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional about other treatment options.
- Ranitidine is an over-the-counter (OTC) and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach.
- OTC ranitidine (ie, Zantac®) 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.
- People taking OTC ranitidine could consider using other OTC medicines approved for their condition. There are multiple drugs on the market that are approved for the same or similar uses as ranitidine.
- The FDA has been investigating NDMA and other nitrosamine impurities in angiotensin II receptor blockers (ARBs) since last year. In the case of ARBs, the FDA has recommended numerous recalls as it discovered unacceptable levels of nitrosamines.
- The FDA is working with international regulators and industry partners to determine the source of this impurity in ranitidine. The agency is examining levels of NDMA in ranitidine and evaluating any possible risk to patients. The FDA will take appropriate measures based on the results of the ongoing investigation and will provide more information as it becomes available.