April 2, 2020 **COM-2020-024**

DRUG SAFETY NOTIFICATION

DATE: 4/1/2020

DRUG NAME: Ranitidine (Zantac™)

DRUG INDICATION: Various conditions where reduction of gastric secretion and acid output is desirable.

SAFETY TOPIC: Removal of all ranitidine products from the market due to an elevated amount of the impurity N-Nitrosodimethylamine (NDMA).

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on April 1, 2020, the U.S. Food and Drug Administration (FDA) announced that all ranitidine products, including over-the-counter (OTC) and prescription products, must be immediately removed from the market.

The decision made by the FDA was based on the results from an ongoing investigation that found that the levels of the impurity N-Nitrosodimethylamine (NDMA) in some ranitidine products increases over time and when stored at temperatures higher than room temperatures, which may result in consumers' exposition to potentially dangerous levels of NMDA.

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. Sustained high levels of exposure may increase the risk of cancer in humans.

Recommendations for Healthcare Providers:

✓ Identify if you have ranitidine products in inventory and immediately stop using and dispensing them.

✓ Contact all patients that received the recalled medication in the previous 90 days and advised them to speak with their physician.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

- ✓ Advise patients to:
  - Stop using the OTC formulations and dispose of them appropriately.
  - Contact their healthcare provider if they have experienced any problems that may be related to taking or using these products.
  - Speak with their healthcare provider about treatment options before stopping a prescription product.
- ✓ Report any adverse event related to this or any other pharmaceutical product to the FDA's MedWatch Adverse Event Reporting program:
  - Online: www.fda.gov/medwatch/report.htm
  - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Additional information can be found at: https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market?utm_campaign=FDA%20Requests%20Removal%20of%20All%20Ranitidine%20Products%20%28Zantac%29&utm_medium=email&utm_source=Eloqua

Best regards,

PharmPix Clinical Department

Reference:

1. Office of the Commissioner. (2020, April 4). FDA Requests Removal of All Ranitidine Products (Zantac) from the Market. Retrieved April 1, 2020, from https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market?utm_campaign=FDA Requests Removal of All Ranitidine Products (Zantac)&utm_medium=email&utm_source=Eloqua

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com