## Glenmark – Recall of ranitidine

- On December 17, 2019, the FDA announced a voluntary, consumer-level recall of prescription ranitidine due to potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA, based on FDA-validated tests.
- 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.
- Glenmark has recalled all 928 unexpired lots of prescription ranitidine 150 mg and 300 mg tablets that can be found in the following NDCs:

| Product Description | NDC# | Expiration Date Range |
|---|---|---|
| Ranitidine 150 mg tablets | 684620-248-60;<br>684620-248-01;<br>684620-248-05 | 12/2019 – 5/2022 |
| Ranitidine 300 mg tablets | 684620-249-30;<br>684620-249-01;<br>684620-249-20 | 12/2019 – 6/2022 |

- Prescription ranitidine is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of gastroesophageal reflux disease, and treatment of endoscopically diagnosed erosive esophagitis.
- Patients taking prescription ranitidine should immediately stop use and talk to their healthcare provider about other treatment options. Multiple drugs are approved for the same or similar uses as ranitidine.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled ranitidine.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- The FDA continues to evaluate the safety of ranitidine and will provide more information as it becomes available. Updates can be found here.
- Contact Glenmark Drug Safety at **1- 888-721- 7115** or e-mail at **GlobalCustomerService@glenmarkpharma.com** for further information regarding this recall.