December 18, 2019

COM-2019-053

Voluntary Nationwide Recall of All Ranitidine Unexpired Lots - Glenmark Pharmaceuticals Inc.

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on December 17, 2019, the U.S. Food and Drug Administration (FDA) issued a statement that Glenmark Pharmaceutical Inc. is recalling all unexpired lots of Ranitidine Tablets, 150 mg and 300 mg, to the consumer level due to the presence of NDMA (N-nitrosodimethylamine) a probable human carcinogen. The affected lots are detailed in following table.

Table 1: Affected Products of Ranitidine

NDC	Description	Expiration date Range
684620-248-60; 684620-248-01, 684620-248-05	Ranitidine Tablets, USP 150mg	12/2019 – 5/2022
684620-249-30; 684620-249-01, 684620-249-20	Ranitidine Tablets, USP 300 mg	12/2019 – 6/2022

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and **advise them to immediately discontinue use**. Patients should contact their physician or

healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. Consumers: questions regarding this recall, refer to the following contact information:
    a. Glenmark Drug Safety by phone at Glenmark customer service center at 1-888-721- 7115, Monday thru Friday, 9:00 am – 6:00 pm, US EST, or e-mail at GlobalCustomerService@glenmarkpharma.com.

Remember that any adverse event related to this or any other pharmaceutical product can be reported 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

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-voluntarily-recalls-all-unexpired-lots-its-ranitidine-tablets-and

Clinical Department