Dr. Reddy's – Recall of ranitidine

- On October 23, 2019, Dr. Reddy's announced the voluntary, consumer-level recall of prescription ranitidine due to potential contamination with N-nitrosodimethylamine (NDMA).

- Dr. Reddy's initially announced retail level recalls for prescription and OTC ranitidine in early October; however, the recall of prescription ranitidine products has been escalated to the **consumer level**. The recall of OTC ranitidine remains at the retail level.

  Prescription Ranitidine Capsules Recalled by Dr. Reddy's

Product Description	NDC#
Ranitidine 150 mg capsules, 60 count bottle	55111-129-60
Ranitidine 150 mg capsules, 500 count bottle	55111-129-05
Ranitidine 300 mg capsules, 30 count bottle	55111-130-30
Ranitidine 300 mg capsules, 100 count bottle	55111-130-01

- Refer to the Dr. Reddy's announcement for a complete list of the OTC recalled ranitidine products.

- Other manufacturers, including Apotex, Perrigo and Sanofi have recently announced retail level recalls of their OTC ranitidine products.

- In September, Sandoz issued a consumer level recall of prescription ranitidine products.

- These recalls follow a recent FDA statement about NDMA impurities detected in ranitidine medicines.

- 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.

- Ranitidine is an OTC and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach. OTC ranitidine 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.

- The FDA does not have scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines at this time. The agency is conducting further tests to determine the risk to consumers.

- Consumers taking OTC ranitidine may consider using other OTC products approved for their condition. To date, the FDA's testing has not found NDMA in alternatives such as Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole) and Prilosec® (omeprazole).

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- Patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional 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 quarantine the product immediately.

- The FDA is continuing to test ranitidine products from multiple manufacturers and assess the possible effect on patients who have been taking ranitidine. Additionally, the FDA recently released a second testing method for manufacturers and regulators to detect and quantify NDMA in ranitidine.

- The FDA will take appropriate measures based on the results of this ongoing investigation. Some manufacturers have chosen to stop distribution of ranitidine as a precautionary measure while the FDA and other international regulators conduct their investigations of the NDMA impurity.

- The FDA continues to evaluate the safety of ranitidine and will provide more information as it becomes available.

- Contact Dr. Reddy's at **1-888-375-3784** for further information regarding this recall.

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