BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Dr. Reddy's confirms recall of all Ranitidine products

24 October 2019 | News

Dr. Reddy's confirms its voluntary nationwide recall of all Ranitidine products in the U.S. Market

Dr. Reddy's Laboratories along with its subsidiaries, together referred to as "Dr. Reddy's confirms it had initiated a voluntary nationwide recall on October 1, 2019, (at the retail level for over-the-counter products and at the consumer level for prescription products) of all of its ranitidine medications sold in US due to confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the FDA. This recall follows the USFDA's caution note alerting patients and health care professionals that NDMA was found in certain samples of ranitidine. To date, Dr. Reddy's has not received any reports of adverse events related to the recall of Dr. Reddy's Ranitidine products. The recall includes all quantities in the US that are within expiry.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) 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 available as an over-the-counter (OTC) and prescription drug. Over-the-counter (OTC) ranitidine tablets are used to relieve heartburn associated with acid indigestion and sour stomach. OTC Ranitidine Tablets are also used to prevent heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages. Prescription ranitidine capsules are prescribed for the short-term treatment of active duodenal ulcer; maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers; treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome and systemic mastocytosis); short-term treatment of active, benign gastric ulcer; maintenance therapy for gastric ulcer patients at reduced dosage after healing of acute ulcers; treatment of GERD (Gastroesophageal reflux disease); treatment of endoscopically diagnosed erosive esophagitis; and for maintenance of healing of erosive esophagitis.

Dr. Reddy's Ranitidine products can be identified by NDC numbers on the product label. All Ranitidine products with expiration dated September 2019 to June 2021 are being recalled:

Description	Strength	Type	Pack
Ranitidine Capsules 150mg, 60	150 mg	Rx	60 ct bottle
Ranitidine Capsules 150mg, 500	150 mg	Rx	500 ct bottle
Ranitidine Capsules 300mg, 30	300 mg	Rx	30 ct bottle
Ranitidine Capsules 300mg, 100	300 mg	Rx	100 ct bottle
Ranitidine Tablets, USP 150mg,190(2x95)Tray (Sam's Club)	150 mg	OTC	190 ct (2x95) tray
Ranitidine Tablets, USP 150mg, 95 (Walgreens)	150 mg	OTC	95 ct bottle
Ranitidine Tablets, USP 150 mg 220 CT Btl (Walmart)	150 mg	OTC	220 ct bottle
Ranitidine Tablets, USP 150mg 50ct Btl (Kroger)	150 mg	OTC	50 ct bottle
Ranitidine Tablets, USP 150mg 24ct Btl (Kroger)	150 mg	OTC	24 ct bottle
Ranitidine Tablets, USP 150mg 65 Ct Btl (Walgreens)	150 mg	OTC	65 ct bottle
Ranitidine Tablets, USP 150 TAB 65ct BTL CP32 (Walmart)	150 mg	OTC	65 ct bottle
Ranitidine Tablets, USP 150 Tab 200Ct Btl (Walgreens)	150 mg	OTC	200 ct bottle
Ranitidine Tablets, USP 150mg Tabs Btl, 24 (Walgreens)	150 mg	OTC	24 ct bottle
Ranitidine Tablets, USP 75 TAB 30ct Bottle NG (CVS)	75 mg	OTC	30 ct bottle
Ranitidine Tablets, USP 75mg Tab 30Ct Btl (Walgreens)	75 mg	OTC	30 ct bottle
Ranitidine Tablets, USP 75mg Tab 80Ct Btl (Walgreens)	75 mg	OTC	80 ct bottle
Ranitidine Tablets, USP 75 TAB 80ct Bottle NG (CVS)	75 mg	OTC	80 ct bottle
Ranitidine Tablets, USP 75 TAB 160ct Bottle NG (CVS)	75 mg	OTC	160 ct bottle

Ranitidine Tablets, USP 75mg 30ct Btl (Kroger)	75 mg	OTC	30 ct bottle
Ranitidine Tablets, USP 150 TAB 24ct BTL (CDMA)	150 mg	OTC	24 ct bottle
Ranitidine Tablets, USP 150 Tablet 130ct Bottle NV (Walmart)	150 mg	OTC	130 ct bottle
Ranitidine Tablets, USP 150 TAB 50ct BTL (CDMA)	150 mg	OTC	50 ct bottle
Ranitidine Tablets, USP 75 Tab 60ct Btl (Dr. Reddy's)	75 mg	OTC	60 ct bottle
Ranitidine Tablets, USP 75 TAB 60ct BTL (CDMA)	75 mg	OTC	60 ct bottle
Ranitidine Tablets, USP 75 TAB 30ct BTL (CDMA)	75 mg	OTC	30 ct bottle
Ranitidine Tablets, USP 150mg Tablets 24ct BTL00 (Dr. Reddy's)	150 mg	OTC	24 ct bottle
Ranitidine Tablets, USP 150 Tab 95ct Btl (HCA)	150 mg	OTC	95 ct bottle
Ranitidine Tablets, USP 150 Tab 220ct Btl (HCA)	150 mg	OTC	220 ct bottle
Ranitidine Tablets, USP Tab 150mg 40ct Bottle (Target)	150 mg	OTC	40 ct bottle
Ranitidine Tablets, USP 150 Tab 24ct Btl (Thirty Madison)	150 mg	OTC	24 ct bottle
Ranitidine Tablets, USP 150 Tab 95ct Btl (Thirty Madison)	150 mg	OTC	95 ct bottle
Ranitidine Tablets, USP 75mg (GeriCare)	75 mg	OTC	All counts
Ranitidine Tablets, USP 150mg (GeriCare)	150 mg	OTC	All counts

If consumers have questions regarding this recall or to report an adverse event, please contact the Company's Medical Information Call Center at 1-888-375-3784 (1-888-DRL-DRUG) between the hours of 8 a.m. to 8 p.m. ET, Monday through Friday. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality concerns experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report 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.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.