DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Dr. Reddy's Confirms its Voluntary Nationwide Recall of All Ranitidine Products in the U.S. Market

October 23, 2019

Dr. Reddy's Laboratories Ltd. intiatiated 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 March 2022** are being recalled:

Description	Strength	Type	Pack	NDC
Ranitidine Capsules 150mg, 60	150 mg	Rx	60 ct bottle	5511112960
Ranitidine Capsules 150mg, 500	150 mg	Rx	500 ct bottle	5511112905
Ranitidine Capsules 300mg, 30	300 mg	Rx	30 ct bottle	5511113030
Ranitidine Capsules 300mg, 100	300 mg	Rx	100 ct bottle	5511113001

Description	Strength	Type	Pack	NDC
Rantidine Tablets, USP 150mg,190(2x95)Tray (Sam's Club)	150 mg	OTC	190 ct (2x95) tray	150062076 (UPC Code 078742089720)
Ranitidine Tablets, USP 150mg, 95 (Walgreens)	150 mg	OTC	95 ct bottle	0363-0010-62
Ranitidine Tablets, USP 150 mg 220 CT Btl (Walmart)	150 mg	OTC	220 ct bottle	49035-404-65
Ranitidine Tablets, USP 150mg 50ct Btl (Kroger)	150 mg	OTC	50 ct bottle	30142-505-50
Ranitidine Tablets, USP 150mg 24ct Btl (Kroger)	150 mg	OTC	24 ct bottle	30142-505-34
Ranitidne Tablets, USP 150mg 65 Ct Btl (Walgreens)	150 mg	OTC	65 ct bottle	0363-0010-61
Ranitidine Tablets, USP 150 TAB 65ct BTL CP32 (Walmart)	150 mg	OTC	65 ct bottle	49035-404-61
Ranitidine Tablets, USP 150 Tab 200Ct Btl (Walgreens)	150 mg	OTC	200 ct bottle	0363-0010-01
Ranitidine Tablets, USP 150mg Tabs Btl, 24 (Walgreens)	150 mg	OTC	24 ct bottle	0363-0010-34
Ranitidine Tablets, USP 75 TAB 30ct Bottle NG (CVS)	75 mg	OTC	30 ct bottle	69842-871-30
Ranitidine Tablets, USP 75mg Tab 30Ct Btl (Walgreens)	75 mg	OTC	30 ct bottle	0363-0131-30
Ranitidine Tablets, USP 75mg Tab 80Ct Btl (Walgreens)	75 mg	OTC	80 ct bottle	0363-0131-80
Ranitidine Tablets, USP 75 TAB 80ct Bottle NG (CVS)	75 mg	OTC	80 ct bottle	69842-871-80
Ranitidine Tablets, USP 75 TAB 160ct Bottle NG (CVS)	75 mg	OTC	160 ct bottle	69842-871-37
Ranitidine Tablets, USP 75mg 30ct Btl (Kroger)	75 mg	OTC	30 ct bottle	30142-131-30
Ranitidine Tablets, USP 150 TAB 24ct BTL (CDMA)	150 mg	OTC	24 ct bottle	63868-480-24
Ranitidine Tablets, USP 150 Tablet 130ct Bottle NV (Walmart)	150 mg	OTC	130 ct bottle	49035-404-13
Ranitidine Tablets, USP 150 TAB 50ct BTL (CDMA)	150 mg	OTC	50 ct bottle	63868-480-50
Ranitidine Tablets, USP 75 Tab 60ct Btl (Dr. Reddy's)	75 mg	OTC	60 ct bottle	55111-131-60
Ranitidine Tablets, USP 75 TAB 60ct BTL (CDMA)	75 mg	OTC	60 ct bottle	63868-482-60
Ranitidine Tablets, USP 75 TAB 30ct BTL (CDMA)	75 mg	OTC	30 ct bottle	63868-482-30
Ranitidine Tablets, USP 150mg Tablets 24ct BTL00 (Dr. Reddy's)	150 mg	OTC	24 ct bottle	55111-404-34

Description	Strength	Type	Pack	NDC
Ranitidine Tablets, USP 150 Tab 95ct Btl (HCA)	150 mg	OTC	95 ct bottle	43598-808-62
Ranitidine Tablets, USP 150 Tab 220ct Btl (HCA)	150 mg	OTC	220 ct bottle	43598-808-65
Ranitidine Tablets, USP Tab 150mg 40ct Bottle (Target)	150 mg	OTC	40 ct bottle	11673-849-40
Ranitidine Tablets, USP 150 Tab 24ct Btl (Thirty Madison)	150 mg	OTC	24 ct bottle	71713-203-02
Ranitidine Tablets, USP 150 Tab 95ct Btl (Thirty Madison)	150 mg	OTC	95 ct bottle	71713-203-05
Ranitidine Tablets, USP 75mg (GeriCare)	75 mg	OTC	All counts	57896-715
Ranitidine Tablets, USP 150mg (GeriCare)	150 mg	OTC	All counts	57896-717

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

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Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-confirms-its-voluntary-nationwide-recall-all-ranitidine-products-us-market?utm_campaign=FDA%20MedWatch%20-%20All%20Ranitidine%20Products%20by%20Dr.%20Reddy%E2%80%99s%3A%20Recall&utm_medium=email&utm_source=Eloqua