DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Novitium Pharma Issues Voluntary National Recall of Ranitidine Hydrochloride Capsules 150mg and 300mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA)

October 25, 2019

Novitium Pharma LLC (Novitium) voluntarily recalled all quantities and lots, within expiry, of Ranitidine Hydrochloride Capsules in the US to the consumer level. Ranitidine Hydrochloride Capsules are being recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA. To date, Novitium has not received any reports of adverse events related to use of the product as part of this recall.

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 Hydrochloride Capsules are indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable. The affected Ranitidine Hydrochloride Capsule can be identified by NDC numbers stated on the product label.

Description	Strength	Type	Pack Size	NDC
Ranitidine Capsules 150mg	150 mg	Rx	60 ct bottle	70954-001-20
Ranitidine Capsules 150mg	150 mg	Rx	500 ct bottle	70954-001-40
Ranitidine Capsules 300mg	300 mg	Rx	30 ct bottle	70954-002-10
Ranitidine Capsules 300mg	300 mg	Rx	100 ct bottle	70954-002-40

H4140_RXRECALLPROV_C

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novitium-pharma-issues-voluntary-national-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg?utm_campaign=FDA%20MedWatch%20-%20Ranitidine%20by%20Novitium%20Pharma&utm_medium=email&utm_source=Eloqua