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Pharmaceutical Product Warning

Zantac (Ranitidine) Safety Information - NDMA Found in Samples of Some Ranitidine Medicines

US FDA has learned that some ranitidine medicines, including some products commonly known as the brand-name drug Zantac, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. 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.

BACKGROUND: Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach. Over-the-counter 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 US FDA has been investigating NDMA and other nitrosamine impurities in blood pressure and heart failure medicines called Angiotensin II Receptor Blockers (ARBs) since last year. In the case of ARBs, the FDA has recommended numerous recalls as it discovered unacceptable levels of nitrosamines.

RECOMMENDATION: The US FDA is not calling for individuals to stop taking ranitidine at this time; however, patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional about other treatment options. People taking ranitidine could consider using other medicines approved for their condition. There are multiple drugs on the market that are approved for the same or similar uses as ranitidine.

https://www.fda.gov/safety/medwatch-safety-alerts-human-medical-products/zantac-ranitidine-safety-information-ndma-found-samples-some-ranitidine-medicines?utm_campaign=FDA%20MedWatch%20Zantac%20%28ranitidine%29%20Safety%20Information&utm_medium=email&utm_source=Eloqua