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FDA announces voluntary recall of ranitidine

BJACH Pharmacy

The U.S. Food and Drug Administration has issued a voluntary recall of Ranitidine (Zantac) hydrochloride capsules -150mg and 300mg – distributed by Sandoz Inc and Apotex. This medication is used to decrease the amount of acid created by the stomach. The recall is due to a nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine. NDMA is classified as a probable human carcinogen – a substance that could cause cancer.

The drug is an over-the-counter (OTC) and prescription medication that prevents and relieves 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 the treatment of gastroesophageal reflux disease.

Not all ranitidine medicines marketed in the U.S. are being recalled. BJACH does NOT dispense ranitidine tablets manufactured by Apotex or Sandoz. FDA is not recommending individuals stop taking all ranitidine medicines at this time. Patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional about other treatment options.