What you need to know about the ranitidine (Zantac) recall?

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On April 1, 2020, the FDA announced that it is mandating all manufacturers to withdraw all ranitidine (Zantac and other brands) prescriptions and over-the-counter (OTC) items from circulation immediately. This is a continuation of the previous advisory that was released in September 2019 that led to several major distributors, such as CVS and Walgreens to remove the product from their shelves. Here is a brief overview of what you should know about this announcement:

Chances are, you may have already read about the Zantac recall last year, or heard about it from your doctor. This recall initially happened because it was discovered that Zantac contained small but significant levels of a substance called N-nitrosodimethylamine (NDMA) (1). This is a substance found in trace amounts in many of the foods we eat, including red meats and dairy products. Unfortunately, some experiments in animals have linked NMDA to the formation of some types of cancer with prolonged exposure (2). Data on cancer risk in human beings are limited, but after initial reports last year, the FDA announced that its own internal testing found significant levels of NMDA presence in Zantac and thus expanded the recall.

While the FDA hasn't release all their data from their internal testing, we can look at our experience with another drug, Valsartan, which was recalled for the same reason. The overall risk for Valsartan was stated as follows: "FDA estimated that if 8,000 people took the highest valsartan dose (320 mg) containing NDMA from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of the 8,000 people" (3).

So if you have taken ranitidine in the past, even if you took it daily for many years, your overall cancer risk is still likely to be very low. If you currently take ranitidine, you should talk to your doctor about what alternative medicines are available, such as Famotidine (Pepcid) or Nizatidine (Axid), which are in the same drug class.

Please note that the recalls apply to all ranitidine preparations.

Woodcock, J. Statement on new testing results, including low levels of impurities in ranitidine drugs. FDA Statement

<https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs> (2019).

Zhu, Y. et al. Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada. Br. J. Nutr. 111, 1109–1117 (2014).

https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products