Zantac / Ranitidine Recall

What: Recall issued by the FDA (Food and Drug Administration)

Who: Children and adults taking any formulation of Zantac/ ranitidine, (even the liquid suspension).

When: Some manufacturers (and stores) voluntarily pulled Zantac/ ranitidine from the shelves in September. As of April 1st this has been formally requested by the FDA. This is the latest step in an ongoing <u>investigation</u> of a contaminant known as N-Nitrosodimethylamine (NDMA). The latest information suggests that the impurity increases in higher heats and with longer storage time or shelf life.

Why: The recall was issued to allow more time for investigation into the source and the increasing levels of NDMA in the medicine. NMDA is classified as a probable carcinogen, meaning that at high and sustained doses there is a probability that someone could develop cancer from this impurity. While low levels of the impurity are found in food and water sources, these low levels, as well as low levels in the medicine, are not thought to increase risk for cancer. The concern is that some formulations of the medicine may have increased levels of the impurity over time.

Should I be worried?

There have not been any reported symptoms or adverse reactions. This is a proactive move to prevent exposure to a potentially harm substance while further investigations are under way. If you believe you have had an adverse reaction these can be reported at www.fda.gov/medwatch/report.htm

What should I do if my child is taking this medicine?

The FDA has recommended to stop taking it. We recognize that your child was taking the medicine for a reason. We would be happy to discuss alternatives, (no NDMA found in these other medicines), or see if your child is ready to come off medication altogether. Please send a message with questions or requesting a visit on the Rivertown Pediatics patient portal. We are doing many of our visits via video conferencing or Telehealth visits now. We would be happy to help you, answer your questions, and make sure to take good care of your child.

For more information, visit: https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market