

Provider Bulletin

News and Information

April 24, 2020

Market Withdrawal Alert - Ranitidine (Zantac) Products

On April 1, 2020, the Food and Drug Administration (FDA) requested a market withdrawal of all remaining over-the-counter (OTC) and prescription ranitidine (Zantac) drugs. This means there will no longer be access to ranitidine drugs in the United States. The market withdrawal stems from an impurity detected in the ranitidine products.

The FDA recommends that patients should stop taking any OTC versions of ranitidine. Patients taking ranitidine as a prescription medication should speak to their prescriber before stopping the medication.

Why was this medication withdrawn from the market?

The FDA has found the contaminant N-nitrosodimethylamine (NDMA) in ranitidine products. The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures. This may result in patient exposure to unacceptable levels of the impurity. When patients are exposed to higher NDMA levels over extended periods of time, it can cause increased risk of cancer.

Where can I find additional information?

The FDA has created a <u>Question and Answer website</u> to address some of the most common questions that patients and health care providers may have. This includes information on safe disposal procedures.

Is UCare reaching out to impacted members and their providers?

We are sending letters to impacted UCare members and their prescribers informing them of this market withdrawal. Your patients may contact you to discuss alternative treatment plans. Alternatives available on all UCare formularies are famotidine, cimetidine, nizatidine, omeprazole, pantoprazole and lansoprazole.

In addition, UCare will be removing ranitidine products from our formularies in accordance with the timelines and processes set out by our regulators.

Note to providers: There have been recent reports of supply shortages for the drug famotidine.

Questions?

If you have further questions, please call UCare's Provider Assistance Center at 612-676-3300 or 1-888-531-1493 toll free or visit ucare.org/providers.