April 30, 2020

Drug Safety Communication: Withdrawal of All Ranitidine Products

Ranitidine is a histamine-2 blocker commonly used as an over-the-counter (OTC) medication to relieve and prevent heartburn. Prescription-strength ranitidine is also used to treat and prevent more serious ulcers in the stomach and intestines. On April 1, 2020, the U.S. Food and Drug Administration (FDA) requested a manufacturer's market withdrawal of ranitidine. This means ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

The FDA is taking this action because FDA laboratory testing results showed that levels of a compound called N-nitrosodimethylamine (NDMA) may increase to unacceptable levels over time and when stored at higher than room temperature. NDMA is an environmental contaminant that is found in water and foods, including dairy products, vegetables, and grilled meats. Its classification as a probable carcinogen is based on studies in animals; studies in humans are very limited.

While the FDA has not observed unacceptable levels of NDMA in any products, the decision was made that ranitidine products should not be available to consumers unless quality can be assured. All ranitidine products, including the oral liquid/syrup, will be withdrawn by their manufacturers and will not be available on the U.S. market. This differs from past actions because this is the first time the FDA is requesting market withdrawal of all ranitidine products.

Health care professionals should advise patients about other treatment options before stopping ranitidine. There are multiple drugs approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. To date, the FDA's testing has not found NDMA in famotidine, cimetidine, esomeprazole, lansoprazole, or omeprazole.

In light of the current response to coronavirus disease 2019 (COVID-19), the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the specific disposal instructions in the medication guide or package insert or follow the FDA's recommended steps, which include ways to safely dispose of these medications at home.

To read the full news release, refer to the "FDA Requests Removal of All Ranitidine Products (Zantac) from the Market" announcement found on the Press Announcements page of the FDA website.