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First Script Prescription Benefit News
for Workers' Compensation

October 2019

Ask The Pharmacist

To suggest a topic, send an email to: AskThePharmacist@cvty.us.com

Why all the recent warnings about Zantac® and blood pressure medicines?

In recent weeks, the U.S. Food and Drug Administration (FDA) reported the discovery of low levels of an impurity in brand, generic, and over-the-counter (OTC) versions of a popular heartburn medication, Zantac (ranitidine Hcl),[1] prompting a flurry of manufacturer recalls, national distribution halts, and product removals from retail pharmacy shelves. Ranitidine is an H2 (histamine-2) blocker approved as a prescription medicine for treatment and prevention of GI ulcers and gastroesophageal reflux disease (GERD). OTC versions are approved for relief of acid indigestion and sour stomach. H2 blockers (like Tagamet®, Pepcid®, and Zantac) act by reducing the amount of acid produced by cells lining the stomach.

The impurity, N-nitrosodimethylamine (NDMA), is the same as that discovered in a number of blood pressure and heart failure medications earlier this year.[2] NDMA is a known environmental contaminant, also found in water, foods, meats, dairy products, and vegetables.

The FDA is currently working to discover the source of NDMA in affected medicines and evaluating whether the low levels discovered in ranitidine to date pose a risk to patients or not. They are not calling for individuals to stop taking ranitidine at this time, but instead, advise patients who may wish to discontinue their use to discuss other treatment options with their health care professional. Persons taking OTC ranitidine products may consider other OTC medications approved for their condition.[1] There are numerous OTC remedies approved for dyspepsia and heartburn.

Because NDMA is a common factor in both of these medication warnings, some now challenge the ability of a pharmaceutical supply chain that is increasingly global, far flung, and complex, as well as the ability of a U.S. regulatory agency to assure the ongoing effectiveness and safety of U.S. medicines from afar.[3] "Unbeknownst to many consumers…80 percent of Active Pharmaceutical Ingredients are produced abroad, the majority in China and India; however, the FDA only inspected one in five registered human drug manufacturing facilities abroad last year," according to Iowa Senator Chuck Grassley.[4]

Since their market introduction, H2 antagonists have yielded to other antiulcer medications in popularity, primarily proton pump inhibitor medications (omeprazole, Nexium®, etc.) with prescription purchases representing approximately 15% of all First Script antiulcer medications. First Script will continue to monitor any developments related to these warnings and take appropriate action as warranted by new findings.

1. https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine
2. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan
3. https://www.washingtonpost.com/opinions/we-rely-on-china-for-pharmaceutical-drugs-thats-a-security-threat/2019/09/10/5f35e1ce-d3ec-11e9-9343-40db57cf6abd_story.html
4. https://www.finance.senate.gov/chairmans-news/grassley-urges-hhs-fda-to-implement-unannounced-inspections-of-foreign-drug-manufacturing-facilities

Governmental Activity by State

Find out more about the governmental updates and potential changes currently being proposed in your state

To find out more about the governmental updates and potential changes currently being proposed in your state, visit the Coventry News and Insights Page each month to read our Government Relations Newsletter. Find this month's newsletter here.

Drug of the Month

Ranitidine Hydrochloride (Hcl)

Ranitidine is a popular antiulcer medication, available in the U.S. as branded Zantac, generic, and over-the-counter (OTC) versions. It was first introduced here in 1981 as Zantac and found early popularity as an alternative to Tagamet® (cimetidine), the first histamine 2 (H2) blocker medication on the U.S. market. Both of these, and other H2 blockers (Pepcid®, Axid®, etc.), work by blocking H2 receptors in specialized, acid-producing cells that line the stomach and reducing the amount of acid they produce.

Prescription versions of ranitidine are FDA approved and used for a range of gastrointestinal disorders, including the short-term and maintenance therapy of gastric and duodenal ulcers, pathological hypersecretory conditions (Zollinger-Ellison Syndrome), treatment of gastro-esophageal reflux disease (GERD), and erosive esophagitis. OTC versions are approved for heartburn and "sour stomach."

In 2016, ranitidine was the 50th most prescribed medication in the U.S. with more than 15 million prescriptions written[1] and appeared on the World Health Organization list of "essential medicines" for health systems.[2] In recent years, H2 blockers have been bypassed in favor of newer antiulcer medications, including the proton pump inhibitors or PPIs (omeprazole, Nexium®, etc.). PPIs are demonstrated to be more effective in longer treatments of GI conditions and in rates of healing for esophageal erosions.[3] H2 blocker medications now represent only 15% of dollar expenses for all antiulcer medications prescribed through First Script.

In recent weeks, ranitidine products have been the subject of a series of FDA warnings, manufacturer recalls, and distribution halts, due to the reported presence of an impurity called N-Nitrosodimethylamine (NDMA). NDMA is described as a "probable carcinogen" in large amounts, but according to the FDA, "the levels of NDMA in ranitidine found in preliminary tests barely exceed amounts found in common foods."[4] The FDA advised patients who are taking prescription ranitidine and want to stop using it to discuss alternatives with their health care provider. Those taking OTC ranitidine can switch to other OTC medicines.

1. https://clincalc.com/DrugStats/Drugs/Ranitidine
2. https://www.who.int/selection_medicines/list/en/
3. Yeomans ND, Tulassay Z, Juhász L, et al. "A comparison of omeprazole with ranitidine for ulcers associated with nonsteroidal antiinflammatory drugs. Acid Suppression Trial: Ranitidine versus Omeprazole for NSAID-associated Ulcer Treatment (ASTRONAUT) Study Group". N. Engl. J. Med. 338 (11): 719–26. (March 1998).
4. https://www.webmd.com/heartburn-gerd/news/20190913/zantac-heartburn-drug-may-contain-carcinogen#2

First Script® Annual Drug Trends Series

Part Four: High Impact Drug Classes

Compared with opioids, other high impact drug classes like topicals, compound kits, combo packs, and specialty medications, represent proportionately low volume. However, they can be associated with exponentially significant costs. Recognizing the trends related to such cost drivers can help promote clinically-appropriate savings. See the infographic.

Clinical Updates

New York Prior Authorization Portal Registration

The NYWCB continues to develop its web-based portal, which will be used for the prior authorization process of non-formulary drugs and is expected in November 2019. To find out more read the bulletin.