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April XX, 2020

First Name/Last Name Address Line 1 Address Line 2 City, ST ZIP Code Here's important news about a medication withdrawal. Action is required.

Dear [Member First Name],

At Medical Mutual, your care is very important to us. Our records indicate that you have filled a prescription for the medication listed below, and we want to make you aware of a recent market withdrawal announced by the Food and Drug Administration (FDA) for all manufacturers of this product:

RANITIDINE HCL

Ranitidine (brand name Zantac) is used as an acid reducer that commonly treats heartburn, acid reflux, gastroesophageal reflux (GERD) and peptic ulcer disease. The FDA has requested the withdrawal of all forms of this medication from the U.S. market because it has been determined that the NDMA (N-Nitrosodimethylamine) in some ranitidine drug products increases to an unacceptable level over time and when stored at higher than room temperatures. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is also a known environmental contaminant also found in water and foods, including meats, dairy products, and vegetables.

What You Need to Know

Talk to your doctor. The FDA recommends that patients speak with their prescriber about other treatment options before stopping the medicine, as there are multiple drug products approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. Some of the many over-the-counter alternatives still available include famotidine (Pepcid), cimetidine (Tagamet), omeprazole (Prilosec OTC), lansoprazole (Prevacid OTC), and esomeprazole (Nexium OTC). You should also talk to your doctor regarding alternative ways to alleviate your symptoms without medication, such as healthy eating and stress management.

Future refills. Because this medication is being withdrawn from the U.S. market, you will no longer be able to fill prescriptions for it. As stated above, please speak with your prescriber about alternative treatment options.

Management of withdrawn medication. Please be aware that your pharmacy won't accept returns for the recalled drug product.

You can safely dispose of the unused medication in your household trash by doing the following:

1. Mix the pills/liquid with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.

- 2. Place the mixture in a container such as a sealed plastic bag.
- 3. Throw away the container in your trash at home.
- 4. Remove or delete all personal information on the prescription labels of empty medication bottles or packaging, then throw them away or recycle them.

If you would like more information, you can view the announcement by visiting the Food and Drug Administration (FDA) website at www.fda.gov. Select the Menu at the top of the screen and click "News and Events" under the Topics section. Select "FDA Newsroom," and then click on "Press Announcements" on the left-hand side of your screen. The announcement regarding Ranitidine can be found under April 1, 2020.

You can also report adverse events or quality problems related to the use of any drug product through the FDA's MedWatch Adverse Events Reporting Program. Call 1-800-FDA-1088 or go to fda.gov/Safety/MedWatch/HowToReport/default.htm.

Sincerely,

Kathyn Canaday

Kathryn Canaday, PharmD Vice President, Pharmacy Management