April 1st, 2020

To All Network Pharmacies

Notification of Drug Market Withdrawal

All Ranitidine Products (Zantac): Press Release - FDA Requests Removal

The U.S. Food and Drug Administration (FDA) provides public notices about drug market withdrawals of FDA-regulated products, whenever it occurs. We are committed to our patients' health and safety. In order to keep you informed we are notifying you of the following drug market withdrawal.

Product	NDC Code	Size	Batch number	Reason	Company
AHP Ranitidine Tablets, USP (all prescription and OTC's formulations and doses)	All applicable NDC's	All sizes	All batches	N-nitrosodimethylamine (NDMA) Impurity	All Companies

We are including the *FDA Press Release/Announcement* for your convenience. Please refer to this document for more information.

Sincerely,
Pharmacy Partnerships Team
Abarca health LLC

The FDA announced it is requesting manufacturers to withdraw all prescription and over the counter (OTC) ranitidine drugs from the market immediately.

This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). NDMA is a probable human carcinogen (a substance that could cause cancer). FDA has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S

Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the stomach. Prescription ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

RECOMMENDATION:

Consumers should:

- Stop taking any taking OTC ranitidine tablets or liquid they currently have
- dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products.

Patients should:

- Patients taking prescription ranitidine should speak with their health care professional about other treatment options before stopping the medicine, as 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 (Pepcid), cimetidine (Tagamet), esomeprazole (Nexium), lansoprazole (Prevacid) or omeprazole (Prilosec).

Consumers and Patients should:

- In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the FDA's recommended steps which include ways to safely dispose of these medications at home.

It is of interest to the FDA that health care professionals and patients report adverse events related to these or other medications through the MedWatch website using the following link: www.fda.gov/MedWatch/report.

At Abarca Health, the health and well-being of our beneficiaries is a priority. For this reason, we emphasize safe practices related to the use of medications in order to obtain the best therapeutic results. For more information on this safety notification, you can access the FDA website https://www.fda.gov/safety or you can contact our Customer Service Department at 1-866-993-7422.

Sincerely,

Pharmacy Partnerships Team
Abarca Health LLC