Magellan Rx Management
2520 Industrial Row Drive
Troy, MI 48084

August 29, 2018

«PRESCRIBER_FIRST_NAME» «PRESCRIBER_LAST_NAME»
«PRESCRIBER_ADDRESS_LINE_1» «PRESCRIBER_ADDRESS_LINE_2»
«PRESCRIBER_CITY», «PRESCRIBER_STATE_ABBREVIATION» «PRESCRIBER_ZIP_CODE»

RE: FDA Recall Class 2 for Hydrochlorothiazide

Dear Dr. «PRESCRIBER_LAST_NAME»,

Magellan Rx Management is the Pharmacy Benefit Management (PBM) Company for Alliant Health Plans. As the PBM, we notify members and prescribers when there has been an FDA Recall or Market Place Withdrawal for medications that are paid for by MagellanRx Management.

The enclosed Memo provides complete details of the current FDA, **Class 2 Recall** including how you can report adverse events or obtain additional information. This recall is at the Lot level and Magellan Rx Management has identified all paid claims that had the potential to be associated with the **Hydrochlorothiazide** recall. We have also notified your patient(s) who were prescribed this medication and had a paid claim on file with Magellan Rx within the timeframe applicable to the recall.

Sincerely,

MagellanRx Management

Enclosures:
Hydrochlorothiazide Recall Notice

For more information regarding this FDA Recall Notification, please be referred to the FDA website: https://www.fda.gov/Safety/Recalls/ucm618583.htm?utm_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20%20Hydrochlorothiazide%20Tablets&utm_medium=email&utm_source=Eloqua

FDA contact information for reporting adverse events/quality complaints online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or call the FDA at 1-800-FDA-1088

Hydrochlorothiazide Tablets USP 12.5 mg by Accord Healthcare: *Recall* - Due to Labeling Mix-up

[Posted 08/28/2018]

AUDIENCE: Pharmacy, Patient

ISSUE: Accord Healthcare Inc. is voluntarily recalling one lot (Lot PW05264 – 46632 Bottles, NDC 16729-182-01) of hydrochlorothiazide tablets USP, 12.5 mg, to the consumer level.

A 100-count bottle of hydrochlorothiazide tablets USP 12.5 mg has been found to contain 100 spironolactone tablets USP 25 mg. Since the individual lot, PW05264, of the product is involved in a potential mix-up of labeling, Accord is recalling this individual lot from the market. Based on findings of both preliminary and interim investigations carried out at the manufacturing site, Accord believes that no other lots of hydrochlorothiazide tablets are involved in this mix-up. Accord became aware of this finding through a product complaint reported from a pharmacy.

BACKGROUND: Spironolactone tablets are indicated in the management of primary hyperaldosteronism, edematous conditions for patients with congestive heart failure, cirrhosis of the liver accompanied by edema and/or ascites, nephrotic syndrome, essential hypertension, hypokalemia, severe heart failure. Use of spironolactone tablets instead of hydrochlorothiazide tablets, poses the risk of contracting hyperkalemia (increase potassium levels) in certain individuals resulting in adverse events that range from limited health consequences to life-threatening situations in certain individuals. To date, Accord has not received any reports of adverse events related to this recall.

Hydrochlorothiazide tablets are indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of hypertension.

Accord's hydrochlorothiazide tablets USP 12.5 mg are light orange to peach colored, round, biconvex tablets debossed with H on one side and 1 on another side. An image of this product is below, if you are unable to view the image, please click this link:

If you are in possession of Accord hydrochlorothiazide that does not match this image or if you are unsure, please return to your pharmacy or healthcare provider for confirmation.

RECOMMENDATION: Accord is notifying its Wholesalers, Distributors and Retailers by letter and is arranging for return of all recalled products. Wholesalers, Distributors, and Retailers that have product which is being recalled should discontinue distribution of the product and notify consumers. Consumers that have the product should return the product to the pharmacy.

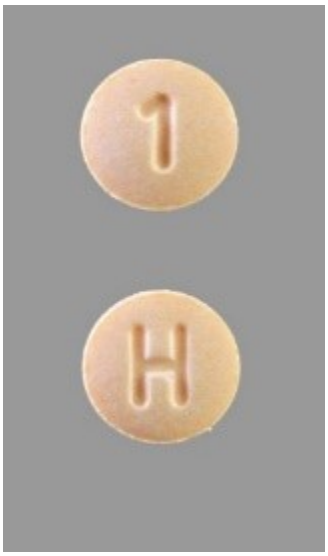
Consumers/Pharmacies with questions regarding this recall can contact Accord Healthcare, Inc. by phone at 1-855-869-1081, fax: 1-817-868-5362 or e-mail at rxrecalls@inmar.com Monday to Friday during business hours 8 am to 5 pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the US Food and Drug Administration.

Product Photo:



Read the safety alert: FDA Link