

URGENT NOTICE

TYPE: Drug Recall

Accord Healthcare has recalled one lot of 12.5-mg hydrochlorothiazide tablets because the 100-count bottle was discovered to contain 100 spironolactone tablets.

Drug Name: **hydrochlorothiazide 12.5-mg tablets**
NDC#: 16729-182-01 Lot#: PW05264

Audience: Consumers

Date: **08/31/2018**



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

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. 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

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 ET. 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.

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