Kidney Community Emergency Response

FDA MedWatch

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Accord Healthcare Inc. Issues Voluntary Nationwide Recall of Hydrochlorothiazide Tablets USP 12.5 Mg Due to Labeling Mix-up

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.

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.

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 either 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 U.S. Food and Drug Administration.

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