Hydrochlorothiazide – Accord Healthcare, Inc.

On August 27, 2018 the U.S. Food and Drug Administration (FDA) announced that Accord Healthcare Inc. is voluntary recalling one lot of Hydrochlorothiazide 12.5mg. This product is being recalled because a 100-count bottle of Hydrochlorothiazide tablets USP 12.5mg has been found to contain 100 Spironolactone tablets USP 25mg. 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. If you are in possession of Accord Hydrochlorothiazide, or if you have questions, please contact your pharmacy.