

August 27, 2018

**URGENT DRUG RECALL**  
**Information for Consumers/Patients**


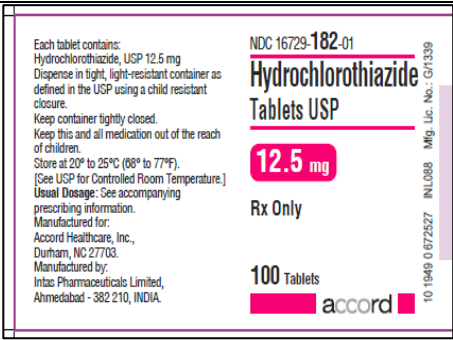
**Voluntary Nationwide Recall of  
Hydrochlorothiazide Tablets 12.5 mg – Lot PW05264**

Dear Valued Consumer:

Accord Healthcare Inc. Issues Voluntary Nationwide Recall of Hydrochlorothiazide Tablets USP 12.5 mg after receiving a product quality complaint. 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 other lots of Hydrochlorothiazide Tablets are not involved in this mix-up.

The product can be identified by the following description: 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.

Product Name	Description	Picture	Product Label
Hydrochlorothiazide tablets, USP 12.5 mg	Light orange to peach colored, round, biconvex tablets debossed with H on one side and 1 on another side		

- If the lot number is PW05264, then return product to the pharmacy.
- If lot number is not available please approach pharmacy or contact Accord Healthcare Inc.\ Inmar 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 9 am to 5 pm EST.
- If the lot number is not available and you verify the product is the Accord Hydrochlorothiazide pills, you may continue taking the medication.
- 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.



- For any additional questions approach your pharmacy or contact Accord Healthcare Inc.\ Inmar by phone at +1-855-869-1081, fax: 1-817-868-5362 or e-mail at [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) Monday to Friday during business hours 9 am to 5 pm EST.

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](http://www.fda.gov/medwatch/report.htm).
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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.**