Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Prinston Pharmaceutical Inc. issues Voluntary Nationwide Recall of Irbesartan and Irbesartan HCTZ Tablets Due to detection of a Trace Amount of Unexpected Impurity, N-nitrosodiethylamine (NDEA) in the Products

For Immediate Release

January 18, 2019

Contact

Consumers

Consumer Contact
888-871-7116

Media

Solco Customer Service
customerservice@solcohealthcare.com (mailto:customerservice@solcohealthcare.com)
1-866-931-9829, Option 5

Announcement

View Product Photos

Prinston Pharmaceutical Inc., dba Solco Healthcare LLC., has initiated a voluntary recall of one (1) lot of Irbesartan and seven (7) lots of Irbesartan HCTZ Tablets to the consumer level due to the detection of trace amount of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.

Prinston is only recalling lots of Irbesartan-containing products that contain N- nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA.

N-nitrosodiethylamine (NDEA) is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Prinston Pharmaceutical Inc. has not received any reports of adverse events related to this recall.

Irbesartan and Irbesartan HCTZ are used to control high blood pressure and for the treatment of heart failure. Irbesartan in combination with amlodipine plus hydrochlorothiazide is used to control high blood pressure.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Irbesartan should continue taking their medication, until their pharmacist provides a replacement, or their doctor prescribes a different medication that treats the same condition as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

The product subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Product	NDC Code	Lot Number	Expiry Dates	Distribution Date
IRBESARTAN TABLETS 300MG 90CT	43547-376-09	331B18009	02/2021	8/9/2018
IRBESARTAN/HCTZ 300MG/12.5MG 30CT TABLETS	43547-331-03	327A18001	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 30 CT TABLETS	43547-331-03	327A18002	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18008	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18009	03/2021	7/10/2018
IRBESARTAN/HCTZ 150MG/12.5MG 30CT	43547-330-03	325D18004	03/2021	7/10/2018
IRBESARTAN/HCTZ 150MG/12.5MG 90CT TABLETS	43547-330-09	325B18004	03/2021	8/24/2018
IRBESARTAN/HCTZ 150MG/12.5MG 30CT TABLETS	43547-330-03	325D18005	03/2021	7/10/2018

Prinston's Irbesartan and Irbesartan/HCTZ tablets were distributed nationwide to wholesale, distributor, repackager and retail customers. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is arranging for return of all recalled products. Instructions for returning recalled products are given in the recall letter.

Retail pharmacies in possession of any unused products: Irbesartan Tablets, 300 mg/90 ct. and Irbesartan-HCTZ Tablets, 300mg/12.5mg, 150mg/12.5mg, in 30 and 90 ct. within the above expiry dates should immediately return the product by following the instructions below:

- Immediately examine your inventory and quarantine product subject to recall.
- Immediately discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.

Return products to:

Eversana
Attn: Returns Department C/O Solco Healthcare 4580 S. Mendenhall,
Memphis, TN 38141

Note: A return label will be provided to you, free of charge. For the call tag, contact customer service via email **customerservice@solcohealthcare.com (mailto:customerservice@solcohealthcare.com)**; fax 1-866-931-0709. Wholesalers: No call necessary, just send debit memo via email or fax to **customerservice@solcohealthcare.com (mailto:customerservice@solcohealthcare.com)**; fax 1-866-931-0709

Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products. Pharmacies and wholesalers that received the impacted products will receive a letter as well as a copy of this press release with their recall notification information.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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 Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

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