PROVIDER ALERT

Prinston Pharmaceutical Inc. Irbesartan and Irbesartan HCTZ Tablets, Drug Recall Notification

To: Alliance Contracted Pharmacies
From: Alliance Pharmacy Services Department
Date: 02/14/2019
Subject: **DRUG RECALL NOTICE**
Products: Medi-Cal, Group Care

Recall Class: *Not yet classified*
Recall Issue Date: 01/18/2019
Recall #: *Not yet classified*
Manufacturer: Prinston Pharmaceutical Inc.
Reason: Impurity detected

DRUG AFFECTED	NDC	LOT #	EXPIRATION DATE
Irbesartan Tablets 300 mg – 90 count	43547-376-09	**331B18009**	02/2021
Irbesartan/HCTZ Tablets 300 mg/12.5 mg – 30 count	43547-331-03	**327A18001**	03/2021
Irbesartan/HCTZ Tablets 300 mg/12.5 mg – 30 count	43547-331-03	**327A18002**	03/2021
Irbesartan/HCTZ Tablets 300 mg/12.5 mg – 90 count	43547-331-09	**327B18008**	03/2021
Irbesartan/HCTZ Tablets 300 mg/12.5 mg – 90 count	43547-331-09	**327B18009**	03/2021
Irbesartan/HCTZ Tablets 150 mg/12.5 mg – 30 count	43547-330-03	**325D18004**	03/2021
Irbesartan/HCTZ Tablets 150 mg/12.5 mg – 90 count	43547-330-09	**325B18004**	03/2021
Irbesartan/HCTZ 150 mg/12.5 mg – 30 count	43547-330-03	**325D18005**	03/2021

Source: www.fda.gov/Safety/Recalls/ucm629627.htm

Image above reflects an example of recalled drug.

Questions? Please call the Alliance Pharmacy Services Department
Monday – Friday, 8 am – 5 pm
Phone Number: **1.510.747.4541**
www.alamedaalliance.org

Prinston Pharmaceuticals Inc., dba Solco Healthcare LLC, has issued a voluntary nationwide recall of one (1) lot, due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the active pharmaceutical ingredient (API) is N-nitrosodietylamine carcinogen. This ingredient 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 by the International Agency for Research on Cancer (IARC). Prinston Pharmaceutical Inc. is only recalling Irbesartan-containing products that contain N-nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the Food and Drug Administration (FDA).

Prinston Pharmaceuticals is notifying its distributors and customers by recall letter and is arranging for return of the one (1) lot recalled product to immediately discontinue distribution of the specific lot and to notify their sub-accounts Prinston Pharmaceuticals Inc. dba Solco Healthcare LLC. Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general questions regarding the return of this product should be directed to:

Solco Consumer Contact
8 am - 5 pm Eastern Time
Toll-Free: **1.888.871.7116**

Consumers, pharmacies, and healthcare facilities that have the recalled product should stop using and dispensing immediately.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- **Online**: Complete and submit the report **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**:
    - Download form **www.fda.gov/MedWatch/getforms.htm**
    - To request a reporting form, please call toll-free at **1.800.332.1088**
    - Please complete and return to the address on the pre-addressed form, or submit by fax to **1.800.FDA.0178 (1.800.332.0178)**