DOCTORS
HEALTHCARE PLANS, INC.

1/18/2019

Drug recall notice for **Irbesartan and Irbesartan HCTZ Tablets**

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

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

What your patients should know:

They may be able to get the same medicine that is not part of the recall or switch to another medicine. Please review treatment options and if a decision is made to switch to an alternative medicine, losartan, olmesartan and telmisartan are covered formulary options.

Please refer your patient to the FDA for the most current updates to this drug or have your patient ask their pharmacy for assistance.

Link to Recall:
https://www.fda.gov/Safety/Recalls/ucm629627.htm?utm_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20Irbesartan%20and%20Irbesartan%20HCTZ%20Tablets%20by%20Prinston&utm_medium=email&utm_source=Eloqua