Prinston – Recall of Irbesartan-Containing Products

- On January 18, 2019, Prinston announced a voluntary, patient-level recall of several lots of irbesartan and irbesartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.

- 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 classification.

    — Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.

- The recalled products are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Irbesartan 300 mg tablets, 90 count bottle	43547-376-09	331B18009 (2/2021)
Irbesartan/HCTZ 300 mg/12.5 mg tablets, 30 count bottle	43547-331-03	327A18001 (3/2021); 327A18002 (3/2021)
Irbesartan/HCTZ 300 mg/12.5 mg tablets, 90 count bottle	43547-331-09	327B18008 (3/2021); 327B18009 (3/2021)
Irbesartan/HCTZ 150 mg/12.5 mg tablets, 30 count bottle	43547-330-03	325D18004 (3/2021); 325D18005 (3/2021)
Irbesartan/HCTZ 150 mg/12.5 mg tablets, 90 count bottle	43547-330-09	325B18004 (3/2021)

- Irbesartan and irbesartan/HCTZ are used to treat hypertension (HTN). Irbesartan is also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and HTN.

- 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 or irbesartan/HCTZ should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled irbesartan or irbesartan/HCTZ.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

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- For more information regarding this recall, contact Solco at **1-888-871-7116**.
    - Solco is a fully owned subsidiary of Prinston and Zhejiang Huahai Pharmaceutical.