## Sandoz – Recall of Losartan/Hydrochlorothiazide

- On November 8, 2018, Sandoz announced a voluntary, consumer-level recall of one lot of losartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine (NDEA) contained in the active pharmaceutical ingredient (API) losartan, manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd.
    - Sandoz's losartan/HCTZ product is manufactured by Lek 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.
- To date, Sandoz has not received any reports of adverse events related to this recall.
- The affected product was not distributed prior to October 8, 2018:

| Product Description | NDC# | Lot# (Expiration Date) |
|---|---|---|
| losartan potassium/ HCTZ, 100 mg/25 mg tablets in 1000-count plastic bottles | 0781-5207-10 | JB8912 (6/2020) |

- Losartan/HCTZ tablets are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.
- Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on losartan/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 losartan/HCTZ.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Sandoz by phone at **1-800-525-8747** or by email at **usdrugsafety.operations@novartis.com**.