

Macleods - Recall of Iosartan/hydrochlorothiazide

- On February 21, 2019, <u>Macleods announced</u> a voluntary, consumer-level recall of one lot of <u>losartan/hydrochlorothiazide</u> (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine (NDEA).
- 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 <u>FDA site</u> for updates regarding angiotensin II receptor blocker recalls.
- The recalled lot was distributed from November 6, 2017 through March 30, 2018:

| Product Description | NDC# | Lot# |
|--|---------------|---------|
| Losartan potassium and HCTZ 100 mg/25 mg tablets | 33342-0052-10 | BLM715A |

- Losartan/HCTZ tablets are used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy.
- 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 Qualanex (appointed company for Macleods) at 1-888-280-2042.



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