Macleods – Recall of losartan-containing products

- On June 20, 2019, Macleods announced a voluntary, consumer-level recall of losartan and losartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of an impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), found in certain lots.
    - This is an expansion to the recall that Macleods announced on February 22, 2019.
- The expanded recall includes the batches distributed by Macleods Pharma USA, Inc. from November 10, 2017 through February 5, 2019.
- Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.

Product Description	NDC#	Lot# (Expiration Date)
Losartan and HCTZ 50 mg/12.5 mg tablets (90 count bottles)	33342-050-10	BLK719A (Sep 2019); BLK720A (Sep 2019); BLK721A (Sep 2019); BLK722A (Sep 2019); BLK723A (Sep 2019); BLK724A (Sep 2019); BLK725A (Oct 2019); BLK726A (Oct 2019); BLK804A (Jan 2020); BLK806A (Jan 2020); BLK825A (Oct 2021); BLK826A (Oct 2021)
Losartan and HCTZ 100 mg/12.5 mg tablets (90 count bottles)	33342-051-10	BLL801A (Dec 2019); BLL802A (Dec 2019); BLL803A (Dec 2019)
Losartan and HCTZ 100 mg/25 mg tablets (90 count bottles)	33342-052-10	BLM716A (Jul 2019); BLM717A (Jul 2019); BLM719A (Aug 2019); BLM720A (Aug 2019); BLM721A (Sep 2019); BLM722A (Sep 2019); BLM723A (Oct 2019); BLM724A (Oct 2019); BLM725A (Oct 2019); BLM726A (Nov 2019); BLM802A (Dec 2019); BLM803A (Dec 2019); BLM825A (Sep 2021); BLM826A (Sep 2021); BLM827A (Sep 2021)
Losartan 50 mg tablets (90 and 1,000 count bottles)	33342-045-10	BLI711A (Nov 2019)
	33342-045-44	BLI710A (Nov 2019)

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- Losartan and 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. Losartan tablets are also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥ 300 mg/g) in patients with type 2 diabetes and a history of 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 a losartan-containing product 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-containing product.

- 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 at **1-888-280-2046**.