



Clifton Health Department Food Recall Notification



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Food/Drug/Pet Recall: Macleods Pharmaceuticals Limited

Macleods Pharmaceuticals Limited has initiated a voluntary recall in the United States, to the patient level, of 32 lots of Losartan Potassium USP Tablets (2 lots of 50mg strength) and Losartan Potassium/Hydrochlorothiazide combination Tablets (12 lots of 50mg/12.5mg strength, 3 lots of 100mg/12.5mg strength and 15 100mg/25mg strength) to the patient level due to the detection of trace amounts of an unexpected impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA). The impurity was found in 32 lots of active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited that is above the US Food & Drug Administration's interim acceptable exposure limit of 9.82 ppm. Based on the available information, the risk of developing cancer in a few patients following long-term use of the product cannot be ruled out.

Losartan Potassium Tablets and Losartan Potassium/Hydrochlorothiazide combination Tablets are indicated to treat hypertension and hypertensive patients with Left Ventricular Hypertrophy. Patients who are on Losartan Potassium Tablets and Losartan Potassium/Hydrochlorothiazide combination Tablets, USP should continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

To date, Macleods Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

The products 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.

Losartan Potassium Tablets 50 mg

NDC Manufacturer Product Description Lot/Batch Expiration Date

33342-045-10 Macleods Pharmaceuticals Limited Losartan Potassium Tablets USP 50mg 90ct BLI711A Nov-19

33342-045-44 Macleods Pharmaceuticals Limited Losartan Potassium Tablets USP 50mg 1000ct BLI710A Nov-19

Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/ 12.5 mg

NDC Manufacturer Product Description Lot/Batch Expiration Date

33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/ 12.5 mg BLK719A Sep-19

33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/ 12.5 mg BLK720A Sep-19

33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/ 12.5 mg BLK721A Sep-19

33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide



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Tablets 50 mg/ 12.5 mg BLK722A Sep-19
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK723A Sep-19
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK724A Sep-19
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK725A Oct-19
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK726A Oct-19
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK804A Jan-20
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK806A Jan-20
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK825A Oct-21
33342-050-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 50 mg/ 12.5 mg BLK826A Oct-21
Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 12.5 mg
NDC Manufacturer Product Description Lot/Batch Expiration Date
33342-051-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 12.5 mg BLL801A Dec-19
33342-051-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 12.5 mg BLL802A Dec-19
33342-051-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 12.5 mg BLL803A Dec-19
Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
NDC Manufacturer Product Description Lot/Batch Expiration Date
33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM716A Jul-19
33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM717A Jul-19
33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM719A Aug-19
33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM720A Aug-19
33342-052-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 25 mg BLM721A Sep-19
33342-052-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 25 mg BLM722A Sep-19



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33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM723A Oct-19
33342-052-10 Macleods
Pharmaceutica Is Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg
BLM724A Oct-19
33342-052-10 Macleods Pharmaceutical Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 25 mg BLM725A Oct-19
33342-052-10 Macleods Pharmaceuticals
Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg BLM726A Nov-19
33342-052-10 Macleods
Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg I 25 mg
BLM802A Dec-19
33342-052-10 Macleods Pharmaceutical Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 25 mg BLM803A Dec-19
33342-052-10 Macleods Pharmaceuticals
Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg BLM825A Sep-21
33342-052-10 Macleods Pharmaceuticals
Limited Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg BLM826A Sep-21
33342-052-10 Macleods Pharmaceuticals Limited Losartan Potassium and Hydrochlorothiazide
Tablets 100 mg/ 25 mg BLM827A Sep-21
Losartan Potassium Tablets 50mg and Losartan Potassium/Hydrochlorothiazide combination
Tablets 50mg/12.5mg, 100mg/25mg and 100mg/12.5mg were distributed nationwide to
Macleods wholesale distributor and retail customers. Macleods Pharmaceuticals Limited is
notifying its distributors and customers by phone and/or in writing to immediately discontinue
distribution of the specific lot being recalled and to notify their sub-accounts. Macleods is
arranging for return of all recalled products to Qualanex. Instructions for returning recalled
products are given in the recall letter.

Consumers with medical questions regarding this recall or to report an adverse event can
contact Macleods Pharmaceuticals Limited at 855-926-3384 (8:00 am - 5:00 pm EST).

If you have any general questions regarding the return of this product, please contact Qualanex
via email at recall@qualanex.com or call 888-280-2046 (7:00 am to 4:00 pm CST Monday to
Friday).

Consumers should also contact their physician or healthcare provider if they have experienced
any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported
to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by
fax.



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- . Complete and submit the report Online
- . Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

For all recalls - <http://www.recalls.gov/recent.html>