Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Macleods Pharmaceuticals Limited Issues Voluntary Nationwide Consumer Level Recall of One Lot (BLM 715A) of Losartan Potassium/Hydrochlorothiazide Combination Tablets 100mg/25mg Due to detection of NDEA (N-Nitrosodiethylamine) Impurity

For Immediate Release

February 22, 2019

Contact

Consumers

Qualanex
recall@qualanex.com (mailto: recall@qualanex.com)
888-280-2042

Announcement

View Product Photos

Macleods Pharmaceuticals Limited is voluntarily recalling one lot of Losartan Potassium/Hydrochlorothiazide combination tablets 100mg/25mg to the consumer level due to the detection of trace amounts of an unexpected impurity (NDEA) found in finished product manufactured with active pharmaceutical ingredient made by Hetero

Labs Limited.

Risk Statement: The impurity detected is N-nitrosodiethylamine (NDEA), which 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 (IARC) classification. Macleods is recalling one lot of Losartan Potassium/Hydrochlorothiazide combination tablets 100mg/25mg that contains NDEA above the interim acceptable daily intake levels released by the FDA.

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

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

The product subject to recall is 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.

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
33342-0052-10	Macleods Pharmaceuticals Limited	Losartan Potassium/ Hydrochlorothiazide combination tablets 100mg/25mg, 90 count bottles	BLM715A	Jul -2019

The representation of the Label is as provided below

Losartan Potassium/Hydrochlorothiazide combination tablets 100mg/25mg 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.

If you have any general questions regarding the return of this product please contact Qualanex via email at **recall@qualanex.com (mailto:recall@qualanex.com)**or call 888-280-2042 (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 associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program by phone, on line, either by regular mail or by fax.

1. Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
2. Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)**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.

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Product Photos

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