



Clifton Health Department Food, Drug, and Pet Recall Notification



Public Health
Prevent. Promote. Protect.

Food/Drug/Pet Recall: Legacy Pharmaceutical Packaging, LLC

Legacy Pharmaceutical Packaging, LLC is recalling 40 repackaged lots of Losartan Tablets USP 25mg, 50mg, and 100mg to the consumer level. This recall was prompted due to Camber Pharmaceuticals, Inc. issuing a Voluntary Nationwide Recall of Losartan Tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer).

NMBA is a potential human carcinogen. To date, Legacy has not received any reports of adverse events related to this recall.

Losartan Potassium USP is a prescription medication used to treat high blood pressure and congestive heart failure and is packaged in 30ct bottles. The identifying NDC numbers associated with Legacy's product are as follows:

Losartan Potassium, USP, 25mg NDC 68645-577-54
Losartan Potassium, USP, 50mg NDC 68645-578-54
Losartan Potassium, USP, 100mg NDC 68645-579-54

The affected Losartan Potassium includes 40 repackaged lots numbers which are listed below:

LEGACY NDC# Name and Strength Count Legacy Lot # Expiry

68645-577-54 Losartan Potassium Tablets USP 25 mg 30 180952 10/2019
68645-577-54 Losartan Potassium Tablets USP 25 mg 30 180953 12/2019
68645-577-54 Losartan Potassium Tablets USP 25 mg 30 181086 09/2019
68645-577-54 Losartan Potassium Tablets USP 25 mg 30 181572 01/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 180921 09/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 180922 10/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 180923 11/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 180924 11/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181118 11/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181119 10/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181407 11/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181408 12/2019
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181573 02/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181725 02/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181726 02/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181948 03/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 181960 02/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 182385 03/2020



Clifton Health Department Food, Drug, and Pet Recall Notification



Public Health
Prevent. Promote. Protect.

68645-578-54 Losartan Potassium Tablets USP 50 mg 30 182386 03/2020
68645-578-54 Losartan Potassium Tablets USP 50 mg 30 182387 03/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 180886 11/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 180887 12/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 180888 12/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 180905 12/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181123 09/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181124 10/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181125 08/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181351 11/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181352 12/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181551 11/2019
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181628 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181629 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181727 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181728 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181890 03/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181891 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 181897 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 182114 03/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 182119 06/2020
68645-579-54 Losartan Potassium Tablets USP 100 mg 30 182120 06/2020

The product can be identified by checking the product name and repackaged lot number on the bottle containing these products.

Losartan Potassium was distributed by pharmacies nationwide. Legacy Pharmaceutical Packaging LLC is notifying its distributors and customers in writing and is arranging/assisting for return of all recalled products to (a) For Distribution Center Level, please return the products to Legacy Pharmaceutical Packaging LLC: (b) For Retail Level, please return the products to Genco: or (c) For Consumer Level, please return the products to the dispensing pharmacy, whichever is applicable. Instructions for returning recalled products are provided in the recall letter.

If you have any medical questions regarding this recall, please contact Camber Pharmaceuticals, Inc. at 1-866-495-1995 (8:00 am - 4:30 pm Eastern Time).

Consumers with questions regarding this recall can contact your dispensing pharmacy during normal business hours. Consumers should 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 either by phone, on line, by regular mail



Clifton Health Department Food, Drug, and Pet Recall Notification



Public Health
Prevent. Promote. Protect.

or by fax.

- . Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- . Regular Mail or Fax: Download form 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

No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from either USDA or 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>