DOCTORS HEALTHCARE PLANS, INC.

Drug recall notice for **Losartan Potassium tablets**

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.

What your patients should know:

They may be able to get the same medicine that is not part of the recall or switch to another medicine. Please review treatment options and if a decision is made to switch to an alternative medicine, irbesartan, olmesartan, telmisartan, valsartan are covered formulary options.

Please refer your patient to the FDA for the most current updates to this drug or have your patient ask their pharmacy for assistance.

https://www.fda.gov/Safety/Recalls/ucm633664.htm?utm_campaign=Legacy%20Pharmaceutical%20Packaging%2C%20LLC%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Losartan%20Potassium%20Tabl&utm_medium=email&utm_source=Eloqua

To determine if your patient's medicine is impacted, check the product name, manufacturer name and NDC. If the information is not listed (NDC or lot number), please contact the pharmacy that filled the prescription.

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.

- **Online:** Complete and submit the report: 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.

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Voluntary Recall Letter:

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

LEGACY NDC#	Name and Strength	Count	Legacy Lot #	Expiry
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
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

LEGACY NDC#	Name and Strength	Count	Legacy Lot #	Expiry
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).

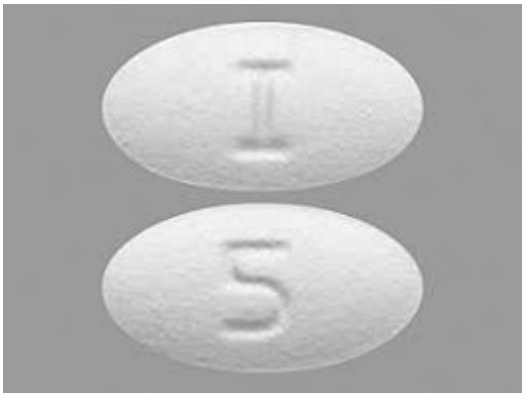
Consumers with questions regarding this recall can contact your **dispensing pharmacy** during normal business hours. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

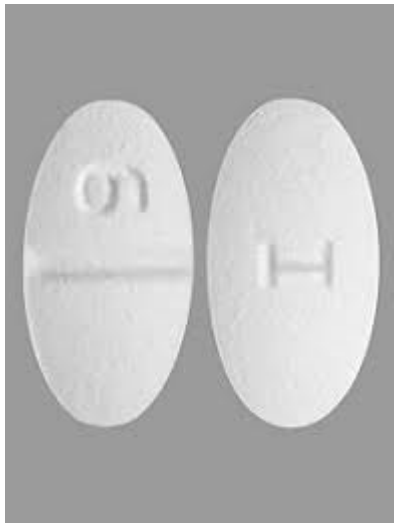
Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

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

- 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GTIN 10368645578542
11142
Rev. 03/2018
N
3 68645 57854 5
Losartan Potassium Tablets USP
50 mg 50 mg 50 mg 50 mg
NDC 68645-578-54
Rx Only
Losartan Potassium Tablets USP
I 50 mg 6
PHARMACIST: Dispense the Patient Information Leaflet separately to each patient.
30 TABLETS
50 mg 50 mg 50 mg 50 mg


GTIN 10368645579549
3 68645 57954 2
N
11144
Rev. 032016
Losartan Potassium Tablets USP
100 mg 100 mg 100 mg 100 mg
NDC 68645-579-54
Rx Only
Losartan Potassium
Tablets USP
H
100 mg
145
PHARMACIST: Dispense the Patient Information Leaflet separately to each patient.
30 TABLETS
100 mg 100 mg 100 mg 100 mg
Take charge of your health by taking your medication properly.
Each film coated tablet contains 100 mg losartan potassium USP.
Usual Adult Dosage: See package insert for full prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Keep container tightly closed.
Protect from light.
WARNING: Keep this and all medications out of the reach of children.
Distributed by:
Wal-Mart
Bentonville, AR 72716
Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854
Packaged by:
Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045

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