DOCTORS HEALTHCARE PLANS, INC.

Drug recall notice for **Losartan Potassium tablets**

Camber Pharmaceuticals, Inc. makers of **Losartan Potassium tablets**, is recalling 87 lots of Losartan Tablets USP 25 mg, 50 mg, and 100 mg to consumer level. This recall was prompted 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, Unit – I (API manufacturer). NMBA is a potential human carcinogen. To date, Camber 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, valsartan and telmisartan 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/ucm632395.htm?utm_campaign=Camber%20Pharmaceuticals%2C%20Inc.%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Losartan%20Potassium%20Tablets&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.

H4140_RXRECALLPROV_C

Voluntary Recall Letter

Camber Pharmaceuticals, Inc. is recalling 87 lots of Losartan Tablets USP 25 mg, 50 mg, and 100 mg to consumer level. This recall was prompted 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, Unit – I (API manufacturer).
NMBA is a potential human carcinogen. To date, Camber 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, 90ct, 500ct, 1000ct bottles. The identifying NDC #s associated with Camber's product as are follows: Losartan 25 mg 31722-700-90, 31722-700-05, 31722-700-10; Losartan 50 mg 31722-701-30, 31722-701-90, 31722-70-10; and Losartan 100 mg 31722-702-30, 31722-702-90, and 31722-702-10.
The affected Losartan includes 87 lot numbers which are listed below:

NDC	Name and Strength	Count	Lot#	Expiry
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17026B	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17050	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17051	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17052	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17053	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17061	Oct-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP18035	Dec-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP18036	Dec-19
31722-700-05	Losartan Potassium Tablets USP 25 mg	500	LOP17026	Sep-19

NDC	Name and Strength	Count	Lot#	Expiry
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17006	May-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17025	Sep-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17068	Oct-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18037	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18038	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18039	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18057	Jan-20
31722-701-30	Losartan Potassium Tablets USP 50 mg	30	LOP17028C	Sep-19
31722-701-30	Losartan Potassium Tablets USP 50 mg	30	LOP17064A	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17027	Sep-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17063	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17093	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17094	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17095	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17097A	Dec-19

NDC	Name and Strength	Count	Lot#	Expiry
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17105	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17107	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17004	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17028B	Sep-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17048	Oct-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17049	Oct-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17056	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17073	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17074	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17076	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17096	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18077A	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18078	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18079	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18080	Feb-20

NDC	Name and Strength	Count	Lot#	Expiry
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18081	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18084	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18095	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18096	Mar-20
31722-702-30	Losartan Potassium Tablets USP 100 mg	30	LOP17011	Aug-19
31722-702-30	Losartan Potassium Tablets USP 100 mg	30	LOP17087	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17012	Aug-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17013	Aug-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17042	Oct-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17043	Oct-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17044	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17045	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18024	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18025	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18026	Dec-19

NDC	Name and Strength	Count	Lot#	Expiry
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18027	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18028	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18029	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18030	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17005	May-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17014	Aug-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17016	Sep-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17023	Sep-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17083	Oct-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17084	Nov-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17085	Nov-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17086	Nov-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18021	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18022	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18023	Dec-19

NDC	Name and Strength	Count	Lot#	Expiry
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18031	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18032	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18033	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18050	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18051	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18109	Mar-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18111	Mar-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18122	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18123	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18124	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18125	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18126	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18127	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18128	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18129	Jun-20

NDC	Name and Strength	Count	Lot#	Expiry
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18130	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18131C	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18133	Jun-20

Losartan Potassium Tablets were distributed Nationwide to Wholesalers, Distributors, Retail Pharmacies, and Mail Order Pharmacies.

Stericycle is notifying Camber's distributors and other customers by recall letter and arranging for return of recalled product of Losartan Potassium Tablets.

Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking the product. Pharmacies and healthcare facilities that have the product being recalled should stop using and dispensing the product immediately.

Consumers with questions regarding this recall can contact Camber Pharmaceuticals' Med Line at 1-866-495-1995 Monday – Friday, 9am – 5pm EST. 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 experienced with the use of this product may be reported to the FDA's MedWatch

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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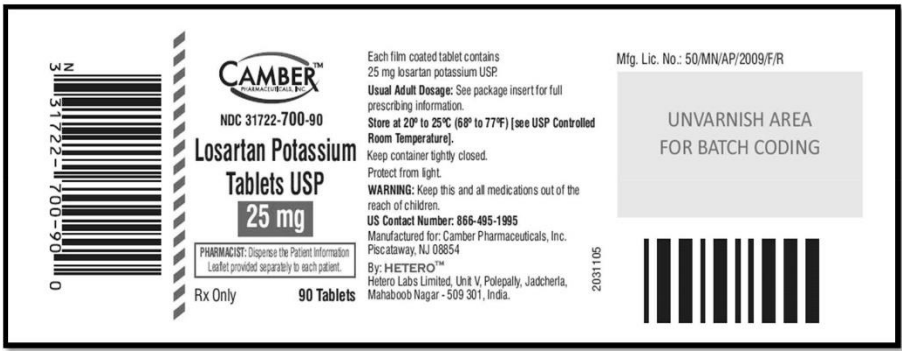
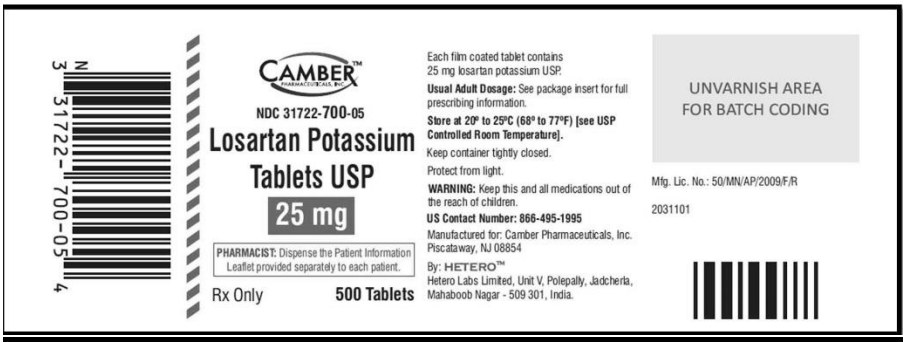
Product Photos




CAMBER
PHARMACEUTICALS, INC.
NDC 31722-700-05
Losartan Potassium
Tablets USP
25 mg
PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.
Rx Only
500 Tablets
Each film coated tablet contains 25 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.
US Contact Number: 866-495-1995
Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854
By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, India.
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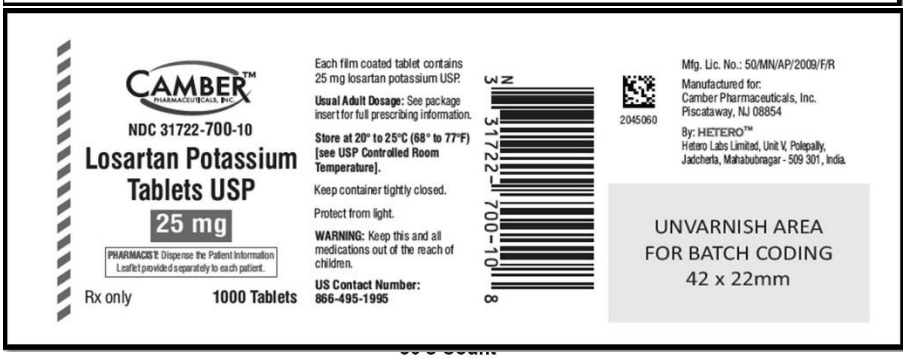
2031101


CAMBER
PHARMACEUTICALS, INC.
NDC 31722-700-10
Losartan Potassium
Tablets USP
25 mg
PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.
Rx only
1000 Tablets
Each film coated tablet contains 25 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.
US Contact Number: 866-495-1995
2045060
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Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854
By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahabubnagar - 509 301, India.
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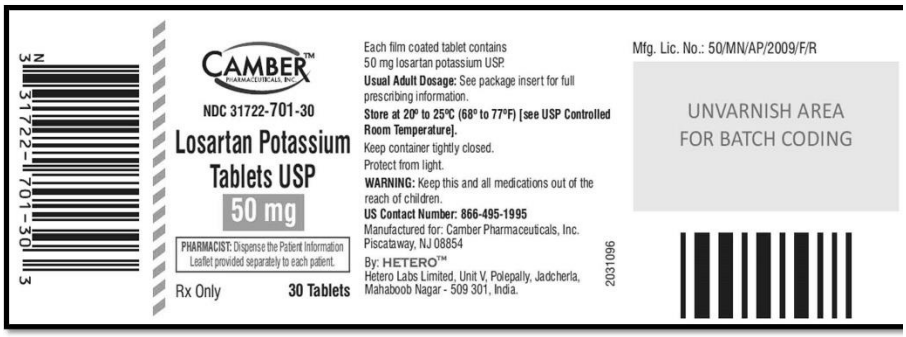
42 x 22mm


CAMBER
PHARMACEUTICALS, INC.
NDC 31722-701-30
Losartan Potassium
Tablets USP
50 mg
PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.
Rx Only
30 Tablets
Each film coated tablet contains 50 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.
US Contact Number: 866-495-1995
Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854
By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, India.
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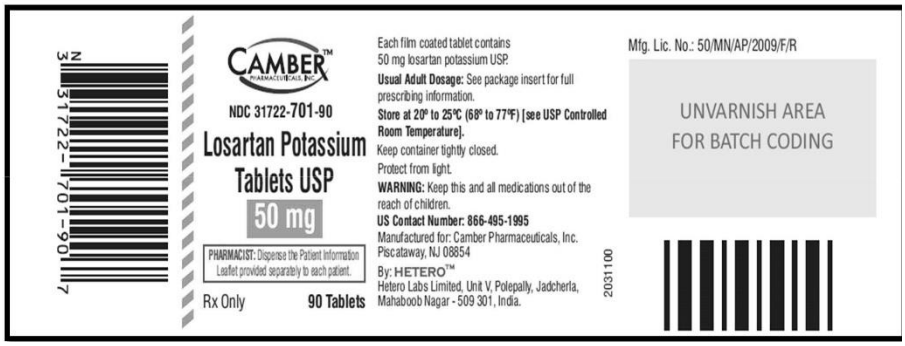
CAMBER
PHARMACEUTICALS, INC.
NDC 31722-701-90
Losartan Potassium
Tablets USP
50 mg
PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.
Rx Only
90 Tablets
Each film coated tablet contains 50 mg losartan potassium USP.
Usual Adult Dosage: See package insert for full 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.
US Contact Number: 866-495-1995
Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854
By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, India.
2031100
Mfg. Lic. No.: 50/MN/AP/2009/F/R
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CAMBER™
PHARMACEUTICALS, INC.

NDC 31722-701-10

Losartan Potassium Tablets USP

50 mg

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Rx only **1000 Tablets**

Each film coated tablet contains 50 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.

US Contact Number:
866-495-1995

3 Z 31722-701-10 5

2045057

Mfg. Lic. No.: 50/MN/AP/2009/F/R

Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

By: HETERO™
Hetero Labs Limited, Unit V, Polepally,
Jadcherla, Mahabubnagar - 509 301, India.

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45 x 28mm

N 31722-702-30 0

CAMBER™
PHARMACEUTICALS, INC.

NDC 31722-702-30

Losartan Potassium Tablets USP

100 mg

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Rx Only **30 Tablets**

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.

US Contact Number: 866-495-1995

Manufactured for: Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla,
Mahaboob Nagar - 509 301, India.

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Mfg. Lic. No.: 50/MN/AP/2009/F/R

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N 31722-702-90 4

CAMBER™
PHARMACEUTICALS, INC.

NDC 31722-702-90

Losartan Potassium Tablets USP

100 mg

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Rx Only **90 Tablets**

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.

US Contact Number: 866-495-1995

Manufactured for: Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla,
Mahaboob Nagar - 509 301, India.

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Mfg. Lic. No.: 50/MN/AP/2009/F/R

2031110

CAMBER™
PHARMACEUTICALS, INC.

NDC 31722-702-10

Losartan Potassium Tablets USP

100 mg

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Rx Only **1000 Tablets**

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.

US Contact Number: 866-495-1995

Manufactured for: Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

By: HETERO™
Hetero Labs Limited, Unit V, Polepally, Jadcherla,
Mahaboob Nagar - 509 301, India.

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