DOCTORS HEALTHCARE PLANS, INC.

Drug recall notice for **Losartan Potassium tablets**

May 3, 2019

Vivimed Life Sciences Pvt Ltd Issues Voluntary Nationwide Recall of Losartan Potassium 25 mg, 50 mg and 100 mg Tablets, USP Due to the Detection of Trace Amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) Impurity

Vivimed Life Sciences Pvt Ltd (Vivimed) is recalling 19 lots of Losartan Potassium Tablets USP 25 mg, 50 mg, and 100 mg to consumer level due to the detection of an N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer) 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 containing high levels of the impurity NMBA cannot be ruled out.

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-market-withdrawals-safety-alerts/vivimed-life-sciences-pvt-ltd-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-50-mg-and

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:

Losartan Potassium is indicated for the treatment of hypertension, hypertensive patients with left ventricular hypertrophy, nephropathy in Type 2 diabetic patients and is packaged in 90-count and 1000-count bottles. The lots were manufactured by Vivimed at its Plant in Alathur, Chennai, India and Distributed by Heritage Pharmaceuticals Inc, East Brunswick NJ (Heritage) .

The identifying NDC #s associated with Heritage distributed product are as follows:
Losartan Tablets 25 mg: 90- count: NDC 23155-644-09, Losartan Tablets 50 mg: 90- count: NDC 23155-645-09; 1000-count: NDC 23155-645-10, Losartan Tablets 100 mg: 90-count- NDC 23155-646-09 1000-count: NDC 23155-646-10.

The affected Losartan Potassium tablets, includes the 19 lot numbers which are listed below:

Product Name	**Lot Number**	**Pack**	**Expiry Date**	**Distributed by**
Losartan Potassium Tablets USP, 25 mg	CLO17006A	90’s	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO17007A	1000's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO17008A	1000's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO17009A	1000's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO17009B	90's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO17010A	90's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO17012A	90's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO17013A	90's	Nov 2019	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO17014A	1000's	Dec 2019	HERITAGE

Product Name	Lot Number	Pack	Expiry Date	Distributed by
Losartan Potassium Tablets USP, 100 mg	CLO17015A	1000's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO17016A	1000's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO17017A	1000's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18001A	1000's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18002A	90's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18002B	1000's	Jan 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18020A	90's	Apr 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18021A	90's	Apr 2020	HERITAGE
Losartan Potassium Tablets USP, 100 mg	CLO18022A	90's	Apr 2020	HERITAGE
Losartan Potassium Tablets USP, 50 mg	CLO18023A	90's	Apr 2020	HERITAGE

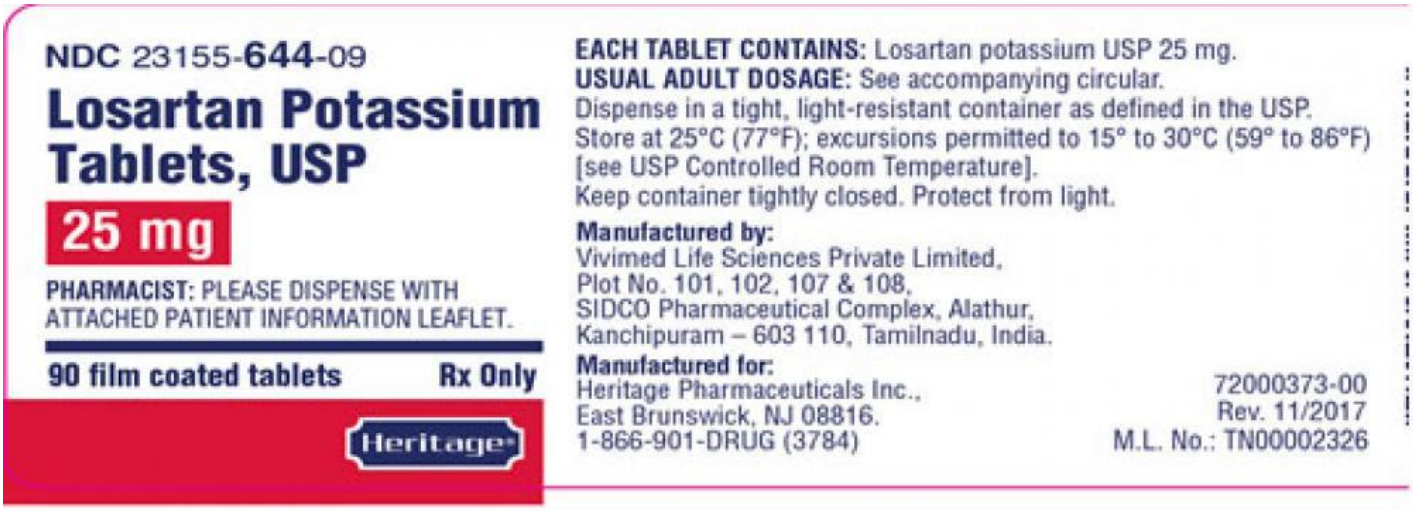
Losartan Potassium Tablets were distributed Nationwide to Wholesalers, Distributors, Retail Pharmacies, and Mail Order Pharmacies.

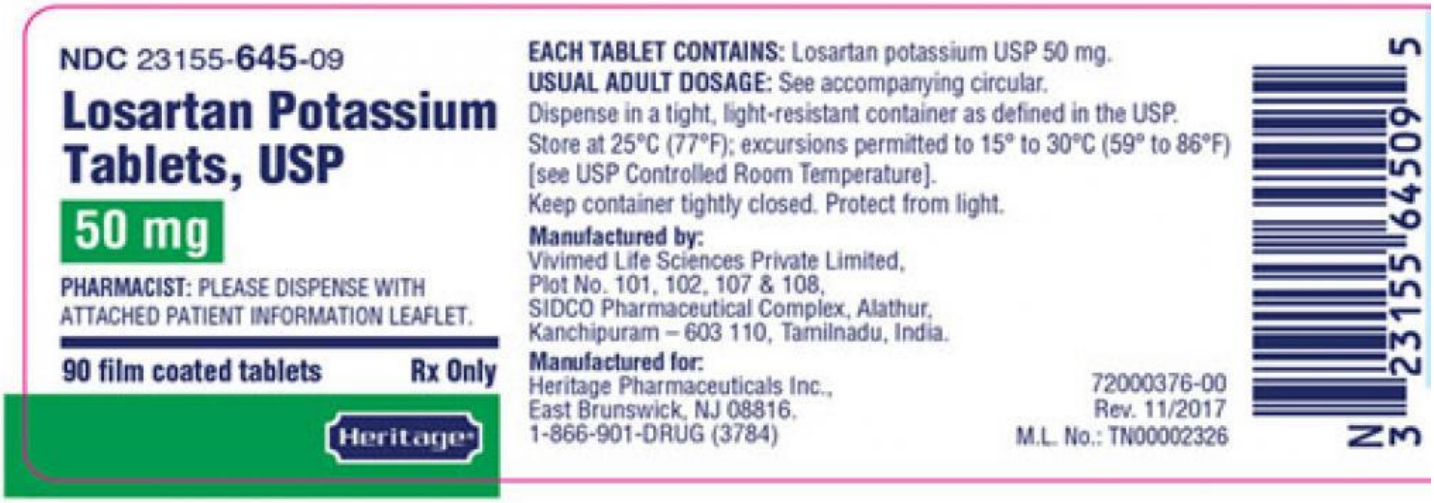
Inmar is notifying distributors and other customers by recall notification and arranging for return of recalled product of Losartan Potassium Tablets from the above lots.

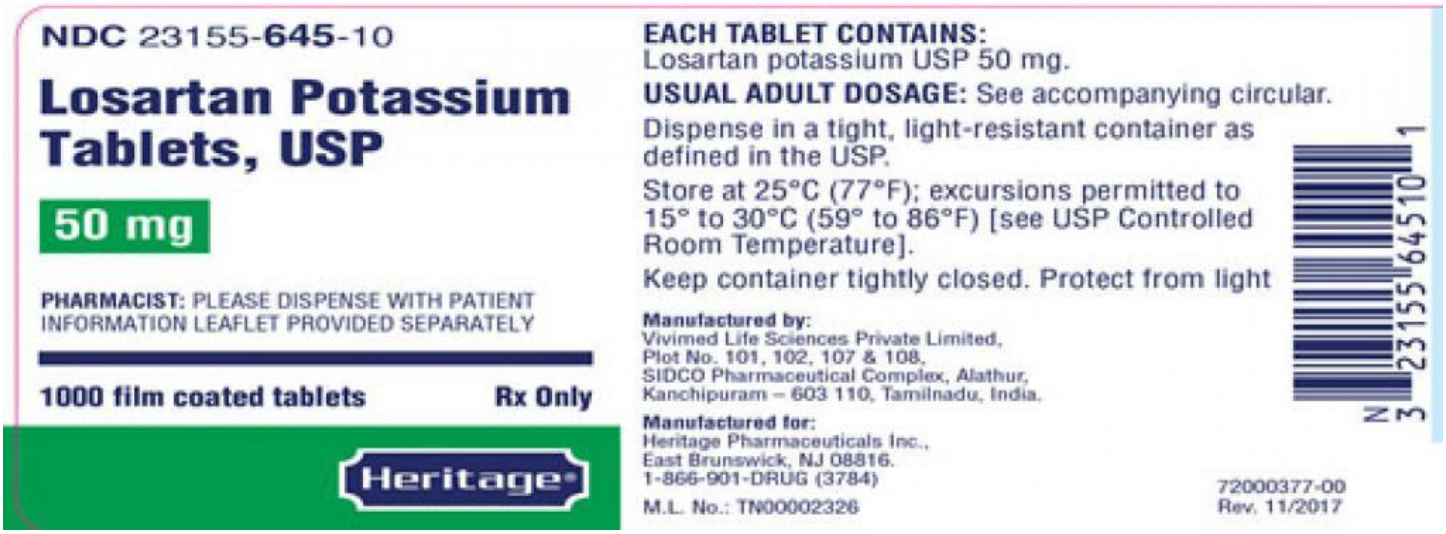
Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking the product. Pharmacies and healthcare facilities that have the product being recalled from above listed lots should stop using and dispensing the product immediately. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Consumers with questions regarding this recall can contact Vivimed C/o Inmar at 1-877-861-3811 Monday – Friday, 9am – 5pm EST.

Product Photos

- 

- 

- 

- NDC 23155-646-09

Losartan Potassium Tablets, USP

100 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET.

90 film coated tablets **Rx Only**

Heritage

EACH TABLET CONTAINS:
Losartan potassium USP 100 mg.

USUAL ADULT DOSAGE: See accompanying circular.

Dispense in a tight, light-resistant container as defined in the USP.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep container tightly closed. Protect from light.

Manufactured by:
Vivimed Life Sciences Private Limited,
Plot No. 101, 102, 107 & 108,
SIDCO Pharmaceutical Complex, Alathur,
Kanchipuram – 603 110, Tamilnadu, India.

Manufactured for:
Heritage Pharmaceuticals Inc.,
East Brunswick, NJ 08816.
1-866-901-DRUG (3784)

M.L. No.: TN00002326

72000379-00
Rev. 11/2017

- NDC 23155-646-10

Losartan Potassium Tablets, USP

100 mg

PHARMACIST: PLEASE DISPENSE WITH PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY

1000 film coated tablets **Rx Only**

Heritage

EACH TABLET CONTAINS:
Losartan potassium USP 100 mg.

USUAL ADULT DOSAGE: See accompanying circular.

Dispense in a tight, light-resistant container as defined in the USP.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep container tightly closed. Protect from light.

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