May 09, 2019

The Press release issued on May 3rd is revised due to revision in first paragraph. The corrected release reads:

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

Contact

Consumers

Vivimed Life Sciences Pvt Ltd
C/O Inmar Inc
Email: rxrecalls@inmar.com
1-877-861-3811

Media

Inmar Inc
Contact Name: Mr. Jack Patterson
Phone# 1-877-861-3811
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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 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.

This product is made by Vivimed at its Plant in Alathur, Chennai, India and Distributed by **Heritage Pharmaceuticals Inc**, East Brunswick NJ (Heritage). To date, neither Vivimed nor Heritage has received any reports of adverse events related to this recall.

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
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.

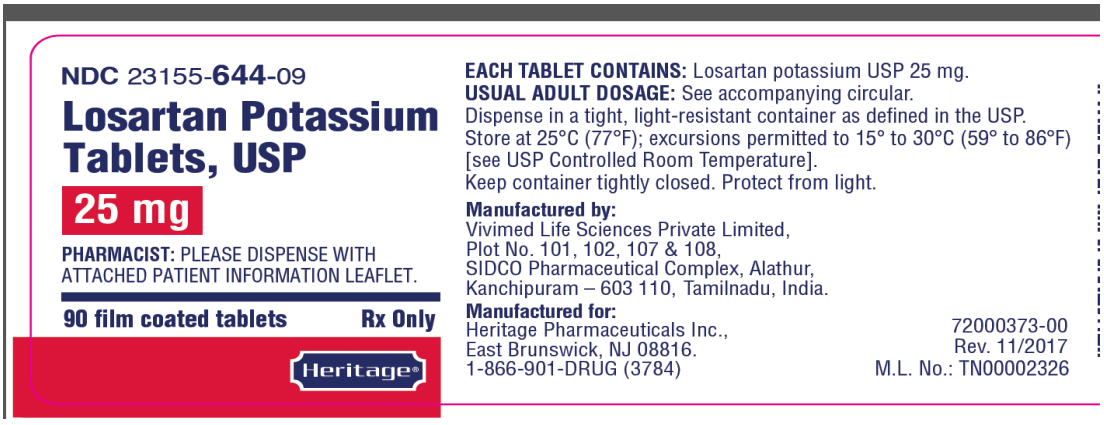
Consumers with questions regarding this recall can contact Vivimed C/o Inmar at 1-877-861-3811 Monday – Friday, 9am – 5pm EST.

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, online, by regular mail or by fax.

- Complete and submit the report Online: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
- Regular Mail or Fax: Download form https://www.fda.gov/safety/medical-product-safety-information/medwatch-safety-alerts-human-medical-products 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.

Labels for Heritage Pharmaceuticals, Inc.



NDC 23155-**645**-10

Losartan Potassium Tablets, USP

50 mg

PHARMACIST: PLEASE DISPENSE WITH PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY

1000 film coated tablets **Rx Only**

Heritage®

EACH TABLET CONTAINS:
Losartan potassium USP 50 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

72000377-00
Rev. 11/2017

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.

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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].

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72000380-00
Rev. 11/2017