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:

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number</th>
<th>Pack</th>
<th>Expiry Date</th>
<th>Distributed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Losartan Potassium Tablets USP, 25 mg</td>
<td>CLO17006A</td>
<td>90's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 50 mg</td>
<td>CLO17007A</td>
<td>1000's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
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<td>CLO17008A</td>
<td>1000's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
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<td>CLO17009A</td>
<td>1000's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 50 mg</td>
<td>CLO17009B</td>
<td>90's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 50 mg</td>
<td>CLO17010A</td>
<td>90's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
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<td>HERITAGE</td>
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<td>90's</td>
<td>Nov 2019</td>
<td>HERITAGE</td>
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<td>1000's</td>
<td>Dec 2019</td>
<td>HERITAGE</td>
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<tr>
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<td>1000's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
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<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
<td>CLO17016A</td>
<td>1000's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
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<tr>
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<td>1000's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
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<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
<td>CLO18001A</td>
<td>1000's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
<td>CLO18002A</td>
<td>90's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
</tr>
<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
<td>CLO18002B</td>
<td>1000's</td>
<td>Jan 2020</td>
<td>HERITAGE</td>
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<tr>
<td>Losartan Potassium Tablets USP, 100 mg</td>
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<td>90's</td>
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<tr>
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<td>90's</td>
<td>Apr 2020</td>
<td>HERITAGE</td>
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<tr>
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<td>Apr 2020</td>
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<td>90's</td>
<td>Apr 2020</td>
<td>HERITAGE</td>
</tr>
</tbody>
</table>

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.

- Regular Mail or Fax: Download form [https://www.fda.gov/safety/medical-product-safety-information/medwatch-safety-alerts-human-medical-products](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.**

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**NDC 23155-644-09**

**Losartan Potassium Tablets, USP**

- **25 mg**
- **Each tablet contains:** Losartan potassium USP 25 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.: TN0002326

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**NDC 23155-645-09**

**Losartan Potassium Tablets, USP**

- **50 mg**
- **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.: TN0002326
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:
Virmedi 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

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:
Virmedi 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

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:
Virmedi 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
72000380-00
Rev. 11/2017