



CLASS I RECALL

05/08/2019

Dear Member,

This communication is about the Vivimed initiated recall of **Losartan Potassium Tablets USP, 25mg, 50mg and 100mg** for 19 lots listed in the table below with their respective NDCs for each fill count. This product was manufactured by Vivimed Life Sciences Private Limited and distributed by Heritage Pharmaceuticals Inc.

Product details with NDC numbers, Dosage, Package counts are listed below:

1. 2315564409 - Losartan Potassium Tablets USP 25mg, 90's
2. 2315564509 - Losartan Potassium Tablets USP 50mg, 90's
3. 2315564 510 - Losartan Potassium Tablets USP 50mg, 1000's
4. 2315564 609 - Losartan Potassium Tablets USP 100mg, 90's
5. 2315564610 - Losartan Potassium Tablets USP 100mg, 1000's

Description	Lot #	Exp. Date	Description	Lot #	Exp. Date
25mg 90's	CLO17006A	11/30/2019	100mg 1000's	CLO17016A	1/31/2020
50mg 1000's	CLO17007A	11/30/2019	100mg 1000's	CLO17017A	1/31/2020
50mg 1000's	CLO17008A	11/30/2019	100mg 1000's	CLO18001A	1/31/2020
50mg 1000's	CLO17009A	11/30/2019	100mg 90's	CLO18002A	1/31/2020
50mg 90's	CLO17009B	11/30/2019	100mg 1000's	CLO18002B	1/31/2020
50mg 90's	CLO17010A	11/30/2019	100mg 90's	CLO18020A	4/30/2020
100mg 90's	CLO17012A	11/30/2019	100mg 90's	CLO18021A	4/30/2020
100mg 90's	CLO17013A	11/30/2019	100mg 90's	CLO18022A	4/30/2020
100mg 1000's	CLO17014A	12/31/2019	50mg 90's	CLO18023A	4/30/2020
100mg 1000's	CLO17015A	01/31/2020			

This recall has been initiated to the **Consumer Level** due to discovery of impurity called NMBA [N-Nitroso-N-methyl-4-aminobutyric acid] which exceeds the FDA requirements.

Losartan Potassium Tablets are generic angiotensin II receptor blocker (ARB) drug product used to treat high blood pressure and heart failure and poses increased risk of cancer to patients with NMBA exposure if present at higher levels.

Vivimed or Heritage are not aware of any adverse patient events resulting from the use of the subject product distributed so far. Heritage began **distributing the subject product lots during March 2018 to wholesalers and distributors in United States and stopped distribution of the product on March 8, 2019** post notification to hold distribution from the manufacturer Vivimed.

We apologize for any inconvenience caused by this product recall. and we appreciate your cooperation and support.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

With this recall you are asked to:

- Immediately examine your inventory and quarantine product lots listed in this recall communication.
- Complete the enclosed "Recall Response Form" and return via fax @ 817-868-5362 or email to rxrecall@inmar.com. The Inmar recall number for this recall is: RCL102-19. In case of any questions, please reach out to Inmar @ 877-861-3811.
- Inmar will provide your store with a recall return package that will include a postage paid product return label to return any recalled product to the address provided in the package.

Mutual SKU #s are: 325-167, 325-191, 308-189, 325-225

Please acknowledge receipt of this Class I Recall and return this letter to NC Mutual Wholesale Drug. **You may return by fax to (919) 596-1453 or by e-mail to: nbasinger@mutualdrug.com**

Store Name _____ Customer # _____

Printed Name _____

Signature _____

Date _____

URGENT: DRUG PRODUCT RECALL NOTIFICATION

May 2, 2019

Dear Valued Customer:

This communication is about the Vivimed initiated recall of **Losartan Potassium Tablets USP, 25mg, 50mg and 100mg** for 19 lots listed in the table below with their respective NDCs for each fill count. This product was manufactured by Vivimed Life Sciences Private Limited and distributed by Heritage Pharmaceuticals Inc.

Product details with NDC numbers, Dosage, Package counts are listed below:

- 2315564409 - Losartan Potassium Tablets USP 25mg, 90's
- 2315564509 - Losartan Potassium Tablets USP 50mg, 90's
- 2315564510 - Losartan Potassium Tablets USP 50mg, 1000's
- 2315564609 - Losartan Potassium Tablets USP 100mg, 90's
- 2315564610 - Losartan Potassium Tablets USP 100mg, 1000's

Description	Lot #	Exp. Date	Description	Lot #	Exp. Date
25mg 90's	CLO17006A	11/30/2019	100mg 1000's	CLO17016A	1/31/2020
50mg 1000's	CLO17007A	11/30/2019	100mg 1000's	CLO17017A	1/31/2020
50mg 1000's	CLO17008A	11/30/2019	100mg 1000's	CLO18001A	1/31/2020
50mg 1000's	CLO17009A	11/30/2019	100mg 90's	CLO18002A	1/31/2020
50mg 90's	CLO17009B	11/30/2019	100mg 1000's	CLO18002B	1/31/2020
50mg 90's	CLO17010A	11/30/2019	100mg 90's	CLO18020A	4/30/2020
100mg 90's	CLO17012A	11/30/2019	100mg 90's	CLO18021A	4/30/2020
100mg 90's	CLO17013A	11/30/2019	100mg 90's	CLO18022A	4/30/2020
100mg 1000's	CLO17014A	12/31/2019	50mg 90's	CLO18023A	4/30/2020
100mg 1000's	CLO17015A	01/31/2020			

This recall has been initiated to the Consumer Level due to discovery of impurity called NMBA [N-Nitroso-N-methyl-4-aminobutyric acid] which exceeds the FDA requirements.

Losartan Potassium Tablets are generic angiotensin II receptor blocker (ARB) drug product used to treat high blood pressure and heart failure and poses increased risk of cancer to patients with NMBA exposure if present at higher levels.

Vivimed or Heritage are not aware of any adverse patient events resulting from the use of the subject product distributed so far. Heritage began distributing the subject product lots during March 2018 to wholesalers and distributors in United States and stopped distribution of the product on March 8, 2019 post notification to hold distribution from the manufacturer Vivimed.

Immediately examine your inventory and quarantine product lots listed in this recall communication. In addition, if you have further distributed this product, please identify your retail customers and notify them at once about this product recall.

Please send a copy of this "Recall Notification Letter" with "Recall Response Form" to your customers and request them to return the "Recall Response Form" to recall service provider [Inmar], as indicated below in this letter. Inmar will provide your retail customers with a recall return package that will include a postage paid product return label to return any recalled product to the address provided below.

Please take the following actions:

- 1) Check your inventory to see if you have any of the recalled product in stock. If so, place the product under quarantine and do not continue to use or distribute.
- 2) Complete the enclosed "Recall Response Form" and return via fax 817-868-5362 or email to rxrecalls@inmar.com. The Inmar recall number for this recall is: RCL102-19
- 3) In case of any questions, please reach out to Inmar at 877-861-3811.
- 4) Return the product to Inmar per following guidelines:
 - Please use the enclosed prepaid return service shipping label to return any recalled inventory.
 - Please include a copy of the "Recall Response Form" along with any returned inventory under this recall.

We apologize for any inconvenience caused by this product recall, and we appreciate your cooperation and support.

This recall is made with the full knowledge of the U.S. Food and Drug Administration.

Sincerely,


Jignesh Kahodariya

Associate Director, Quality and Compliance

See product label below for ease of identifying the product.

NDC 23155-644-09 Losartan Potassium Tablets, USP 25 mg PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET. 90 film coated tablets Rx Only 	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) 72000373-00 Rev. 11/2017 M.L. No.: TN00002326
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NDC 23155-645-09

**Losartan Potassium
Tablets, USP****50 mg**PHARMACIST: PLEASE DISPENSE WITH
ATTACHED PATIENT INFORMATION LEAFLET.

90 film coated tablets Rx Only



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)

72000376-00
Rev. 11/2017
M.L. No.: TN00002326



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



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



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



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

72000380-00
Rev. 11/2017



RECALL RETURN RESPONSE FORM**Product Name: Losartan Potassium Tablets USP, 25mg, 50mg and 100mg**

NDC:	2315564409 - 25mg 90's	2315564510 - 50mg 1000's	2315564509 - 50mg 90's
	2315564609 - 100mg 90's	2315564610 - 100mg 1000's	

Lot Numbers - Please refer to Recall Notification letter.**Please check ALL appropriate boxes.**

- ☐ I have read and understand the recall instructions provided in the recall notification letter dated 05/02/2019.
- ☐ I have identified and notified my customers that were shipped, or may have been shipped, this product _____ (please **specify date and method of notification**); _____

Any adverse events associated with recalled product? ☐ Yes ☐ No.

If yes, please explain: _____ [Attach additional sheets if needed]

Please check the appropriate box(es) to describe your business

- ☐ wholesaler/distributor ☐ pharmacy - retail ☐ Other: _____
- ☐ hospital/medical facility ☐ hospital pharmacies

Please email and or fax your completed form to (Vivimed, c/o Inmar, Recall Number: RCL102-19, Email: rxrecalls@inmar.com, Fax No.: 817-868-5362)

Customer information:**Company DEA:** _____**Company Name:** _____**Company Address:** _____**Company City:** _____ **State:** _____ **Zip:** _____**Signature:** _____ **Print name** _____ **Date:** _____**Email:** _____ **Phone Number:** _____*If you did not purchased directly from Heritage Pharmaceuticals, please complete the below***Company you purchased product from (Wholesaler):** _____**Wholesaler City\ State** _____ **Wholesaler DEA#** _____**Form Completed by:** _____ **Title:** _____

Please list inventory in your possession to be returned [Attach additional sheets if needed].

Lot #	Sealed Bottles Bottles count	Unsealed / Partial Bottles	
		Bottle count	Tablets count