

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – CONSUMER LEVEL - INITIATED 04/24/2019

LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg

RECALLED BY:

Teva Pharmaceuticals USA, Inc.

Parsippany, NJ 07054

Dear Golden State Medical Supply, Inc.:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the **CONSUMER LEVEL** specific lots of LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg tablets, given in the table below. The lots being recalled were sold exclusively to you as bulk containers of tablets by Actavis Pharma, Inc. USA under the Watson Pharmaceuticals label. It is our understanding that you have packaged the tablets as finished drug product and shipped the product to your customers under the Golden State Medical Supply, Inc. label, NDC(s) and lot number(s).

Bulk Product Description	Bulk Product NDC	Bulk Product Lot Number	Bulk Exp. Date	Number of Bulk Containers Shipped	Ship Date
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1139277A	6/30/2019	2,750	10/21/2016
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1139278A	6/30/2019	2,918	10/21/2016
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1169785A	2/29/2020	2,870	5/3/2017
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1177559A	2/29/2020	2,900	5/3/2017
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1184800A	2/29/2020	2,946	5/3/2017
LOSARTAN POTASSIUM USP 25 mg Tablets BULK	0591-3745-00	1184801A	2/29/2020	2,972	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1124202A	6/30/2019	698	9/9/2016
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1124203A	6/30/2019	737	9/9/2016
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1124204A	6/30/2019	733	9/9/2016
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1124205A	6/30/2019	732	9/9/2016
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163861A	12/31/2019	724	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163866A	1/31/2020	727	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163867A	1/31/2020	734	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163868A	1/31/2020	731	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163869A	1/31/2020	729	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163870A	1/31/2020	731	4/10/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163876A	1/31/2020	727	4/21/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163877A	1/31/2020	729	4/21/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163878A	1/31/2020	732	4/21/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163879A	1/31/2020	732	4/21/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163891A	1/31/2020	728	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163896A	1/31/2020	727	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163902A	2/29/2020	723	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163907A	1/31/2020	734	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1163908A	1/31/2020	727	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169762A	1/31/2020	734	5/3/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169763A	1/31/2020	730	5/12/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169764A	1/31/2020	733	5/12/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169767A	2/29/2020	729	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169768A	2/29/2020	737	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169769A	2/29/2020	733	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169770A	2/29/2020	735	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169771A	2/29/2020	733	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1169772A	2/29/2020	737	5/19/2017
LOSARTAN POTASSIUM USP 100 mg Tablets BULK	0591-3747-00	1177532A	2/29/2020	734	5/19/2017

This voluntary recall was prompted due to the detection of an impurity identified as N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) that is present in the active pharmaceutical ingredient. The active ingredient is manufactured by Hetero Labs Limited (Unit-I), India.

Based on the available information, the risk of cancer in a few patients following long term use of the product containing high levels of the impurity NMBA cannot be ruled out. Patients are advised to consult with their pharmacist, healthcare provider or physician who can advise them about an alternative treatment prior to discontinuation of the medication. The adverse health consequence may be higher if the treatment is stopped without any alternative intervention, than the potential cancer risk of continuing losartan treatment for a short period of time.

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – CONSUMER LEVEL - INITIATED 04/24/2019

LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the referenced bulk lots of LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg (which includes your finished product lots that used the above bulk lots).
- Our records indicate that Actavis Pharma, Inc. USA shipped these bulk lots to you from 9/9/2016 through 5/19/2017.
- Immediately discontinue distribution of product lots affected by the recall.
- **Carry out a SUB-RECALL to your Retail / Direct Accounts (sub-accounts). Please use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.**
- **An information letter for Consumers/Patients/Caregivers concerning this voluntary recall is included with this notification. Please provide the letter to your sub-accounts to give to their Consumers/Patients/Caregivers.**
- Even if there is **no** recalled product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

Inmar, 635 Vine Street, Winston Salem, NC 27101

Email address: tevarecalls@inmar.com

FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label, if requested on your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT	
Product Returns (from GSMS):	
Contact Inmar at: 877-789-2065 (Hours of Operation: 9 am to 5 pm Eastern Time)	
Recall Stock Response forms Contact Inmar at 877-789-2065 or acquire it from clsnetlink.com .	
Medical-related Questions or to report an Adverse Event:	
Contact Medical Information at: 888-838-2872, option 3, then, option 4	
Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week	
Product Quality Complaint-related Questions:	
Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3	
(Hours of Operation: Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).	
Customer Service-related Questions:	
Contact Teva Customer Service: 888-838-2872, option 2	
(Hours of Operation: Live calls received: Monday-Friday, 8:30 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).	
FDA contact information for reporting adverse events/quality complaints:	
Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088	

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Attachments/ Stock Response Form; Letter - Information for Consumers/Patients/Caregivers

Teva Pharmaceuticals USA, Inc.

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LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg

STOCK RESPONSE FORM – Page 1 of 3

Even if there is no recalled product to return, promptly complete the recall stock response form and return by mail, email, or FAX to Inmar:

FAX to: 817-868-5362 or EMAIL to tevarecalls@inmar.com or MAIL to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101

Please fill out completely

Date: _____

Golden State Medical Supply, Inc. ONLY: Does this response include all your DC locations?

☐ YES

☐ NO

Customer/Store Name: _____

DEA #: _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Teva Bulk - LOSARTAN POTASSIUM TABLETS USP 25 mg and 100 mg				
Bulk Product NDC	Strength	Bulk Product Lot Number	Bulk Exp. Date	Quantity of Tablets in Bulk Containers to be Returned
0591-3745-00	25 mg	1139277A	6/30/2019	
0591-3745-00	25 mg	1139278A	6/30/2019	
0591-3745-00	25 mg	1169785A	2/29/2020	
0591-3745-00	25 mg	1177559A	2/29/2020	
0591-3745-00	25 mg	1184800A	2/29/2020	
0591-3745-00	25 mg	1184801A	2/29/2020	
0591-3747-00	100 mg	1124202A	6/30/2019	
0591-3747-00	100 mg	1124203A	6/30/2019	
0591-3747-00	100 mg	1124204A	6/30/2019	
0591-3747-00	100 mg	1124205A	6/30/2019	
0591-3747-00	100 mg	1163861A	12/31/2019	
0591-3747-00	100 mg	1163866A	1/31/2020	
0591-3747-00	100 mg	1163867A	1/31/2020	
0591-3747-00	100 mg	1163868A	1/31/2020	
0591-3747-00	100 mg	1163869A	1/31/2020	
0591-3747-00	100 mg	1163870A	1/31/2020	
0591-3747-00	100 mg	1163876A	1/31/2020	
0591-3747-00	100 mg	1163877A	1/31/2020	
0591-3747-00	100 mg	1163878A	1/31/2020	
0591-3747-00	100 mg	1163879A	1/31/2020	
0591-3747-00	100 mg	1163891A	1/31/2020	
0591-3747-00	100 mg	1163896A	1/31/2020	
0591-3747-00	100 mg	1163902A	2/29/2020	
0591-3747-00	100 mg	1163907A	1/31/2020	
0591-3747-00	100 mg	1163908A	1/31/2020	
0591-3747-00	100 mg	1169762A	1/31/2020	
0591-3747-00	100 mg	1169763A	1/31/2020	
0591-3747-00	100 mg	1169764A	1/31/2020	
0591-3747-00	100 mg	1169767A	2/29/2020	
0591-3747-00	100 mg	1169768A	2/29/2020	
0591-3747-00	100 mg	1169769A	2/29/2020	
0591-3747-00	100 mg	1169770A	2/29/2020	
0591-3747-00	100 mg	1169771A	2/29/2020	
0591-3747-00	100 mg	1169772A	2/29/2020	
0591-3747-00	100 mg	1177532A	2/29/2020	

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STOCK RESPONSE FORM – Page 2 of 3

For Golden State Medical Supply packaging configurations please complete this table, too for any inventory you have on hand.

Golden State Medical Supply, Inc. Finished Goods (FG) Packaging					
Teva Bulk Lot #	GSMS FG NDCs	GSMS FG NDC Description	GSMS FG Product Lots	GSMS FG Expiration Dates	Quantity of Bottles to be Returned (Count partials as 1)
1124202A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS014045	06/2019	
1124203A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS014305	06/2019	
1124204A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS014054	06/2019	
1124205A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS014044	06/2019	
1139277A	60429-316-10	Losartan Potassium, Tablets, USP, 25 mg, 1,000 Count Bottle	GS014817	06/2019	
1139278A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS015172	06/2019	
1139278A	60429-316-10	Losartan Potassium, Tablets, USP, 25 mg, 1,000 Count Bottle	GS015204	06/2019	
1163861A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016338	12/2019	
1163866A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016341	01/2020	
1163867A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016342	01/2020	
1163868A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016343	01/2020	
1163869A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016344	01/2020	
1163870A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016345	01/2020	
1163876A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS016535	01/2020	
1163877A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS016524	01/2020	
1163878A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016539	01/2020	
1163879A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016969	01/2020	
1163891A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS016973	01/2020	
1163896A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS017337	01/2020	
1163902A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017384	02/2020	
1163907A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017385	01/2020	
1163908A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017539	01/2020	
1169762A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017540	01/2020	
1169763A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017543	01/2020	
1169764A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017542	01/2020	
1169767A	60429-318-10	Losartan Potassium, Tablets, USP, 100 mg, 1,000 Count Bottle	GS018524	02/2020	
1169768A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017984	02/2020	
1169769A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017985	02/2020	
1169770A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS017986	02/2020	
1169771A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS018263	02/2020	
1169772A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS018264	02/2020	
1169785A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS017634	02/2020	
1169785A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS017653	02/2020	
1169785A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS017980	02/2020	
1169785A	60429-316-30	Losartan Potassium, Tablets, USP, 25 mg, 30 Count Bottle	GS017981	02/2020	
1177532A	60429-318-90	Losartan Potassium, Tablets, USP, 100 mg, 90 Count Bottle	GS018265	02/2020	
1177559A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS016726	02/2020	
1177559A	60429-316-30	Losartan Potassium, Tablets, USP, 25 mg, 30 Count Bottle	GS016958	02/2020	
1177559A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS017045	02/2020	
1177559A	60429-316-90	Losartan Potassium, Tablets, USP, 25 mg, 90 Count Bottle	GS017276	02/2020	
1177559A	60429-316-30	Losartan Potassium, Tablets, USP, 25 mg, 30 Count Bottle	GS017341	02/2020	
1177559A	60429-316-10	Losartan Potassium, Tablets, USP, 25 mg, 1,000 Count Bottle	GS018318	02/2020	
1184800A	60429-316-10	Losartan Potassium, Tablets, USP, 25 mg, 1,000 Count Bottle	GS017342	02/2020	
1184801A	60429-316-10	Losartan Potassium, Tablets, USP, 25 mg, 1,000 Count Bottle	GS017808	02/2020	

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LOSARTAN POTASSIUM TABLETS, USP, 25 mg and 100 mg

STOCK RESPONSE FORM – Page 3 of 3

I have checked my stock and:

..... I **do not** have stock of the recalled item(s) OR

..... I **do** have stock of the recalled item(s) listed above.

Please send me _____

shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

CONTACT INFORMATION AND CREDIT

Product Returns (from GSMS):

Contact Inmar at: 877-789-2065 (Hours of Operation: 9 am to 5 pm Eastern Time)

Recall Stock Response forms Contact Inmar at 877-789-2065 or acquire it from clsnetlink.com.

Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4
Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week

Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3
(Hours of Operation: Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).

Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 2
(Hours of Operation: Live calls received: Monday-Friday, 8:30 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).

FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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