COMPANY ANNOUNCEMENT

Teva Pharmaceuticals USA, Inc. Expands Voluntary Nationwide Recall of Losartan Potassium to 50 mg and 100 mg Tablets USP, Sold Exclusively to Golden State Medical Supply, Inc.

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

June 10, 2019

FDA Publish Date:

June 11, 2019

Product Type:

Drugs
Generic Drugs

Reason for Announcement:

Detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA)

Company Name:

Teva Pharmaceuticals USA, Inc.

Brand Name:

GSMS Inc.

Product Description:

Losartan potassium tablets

Company Announcement

Teva Pharmaceuticals USA, Inc. has expanded its voluntary consumer-level recall originally initiated on April 25, 2019 in the United States of losartan potassium tablets. This expanded recall includes six (6) lots of bulk losartan potassium USP Tablets (two lots of 50 mg strength

and four lots of 100 mg strength) due to the detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) – that is above the US Food & Drug Administration's interim acceptable exposure limit of 9.82 ppm. The source of the NMBA impurity was detected in one lot of active pharmaceutical ingredient (API), manufactured by Hetero Labs Limited, which was used in the manufacturing of the six (6) bulk lots of these drug products. Based on the available information, there is a potential risk of developing cancer in a few patients following long-term use of products containing high levels of NMBA.

For more information on the previous recall initiated on April 25, 2019, click here. (https://www.tevausa.com/news-and-media/press-releases/teva-pharmaceuticals-usa-inc.-issues-voluntary-nationwide-recall-of-losartan-potassium-25-mg-and-10/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Losartan potassium is indicated for the treatment of hypertension, hypertensive patients with left ventricular hypertrophy, and nephropathy in Type 2 diabetic patients. The bulk lots were sold exclusively to Golden State Medical Supply, Inc. of Camarillo, California. Golden State Medical Supply, Inc. packaged these bulk products under its own label and distributed retail bottles of 30, 90 and 1000 tablets to their customers.

The affected losartan potassium tablets being recalled are described as:

- Losartan potassium tablets, USP 50 mg, are green, film-coated, oval-shaped biconvex tablets with "LK 50" on one side and ">" on the other side.
- Losartan potassium tablets, USP 100 mg, are dark green, film-coated, oval-shaped biconvex tablets with "LK100" on one side and ">" on the other side.

Teva promptly notified Golden State Medical Supply, Inc. of the presence of the impurity in Hetero's API and Teva will recall six (6) lots of bulk losartan potassium tablets sold to that company. The tablets, which have been packaged and sold by Golden State Medical Supply, Inc., will be sub-recalled from their customers and patients. Distributors and retailers that have product being recalled should immediately stop distribution, quarantine all remaining product in their control, and return the recalled product per the instructions given to them by Golden State Medical Supply, Inc.

Patients taking losartan potassium tablets are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. The immediate risk of harm to a patient's health is likely to be higher if the medicine is stopped abruptly without any alternative treatment. For full drug product information, please refer to the full prescribing information for losartan potassium tablets USP.

Customers and patients with medical-related questions, who wish to report an adverse event, or quality issues about the Teva products being recalled under the Golden State Medical Supply label should contact Teva Medical Information by phone at: 888-838-2872, option 3, then, option 4. Live calls are received Monday-Friday, 9:00AM-5:00PM Eastern Time with voicemail available 24 hours/day, 7 days/week or by email at druginfo@tevapharm.com (mailto:druginfo@tevapharm.com).

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.

- Complete and submit the report Online (http://wcms-internet.fda.gov/node/360543)
- Regular Mail or Fax: Download form (http://wcms-internet.fda.gov/node/360547) 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.

Lots Under Voluntary Recall

The finished product lots that are included in this voluntary recall and listed below were sold by Teva in bulk containers. The bulk tablet lots were repackaged into seven (7) finished product lots for further distribution by Golden State Medical Supply under its product label.

GSMS FG NDCs	GSMS FG NDC Description	GSMS FG Product Lots	GSMS FG Expiration Dates
60429-317-10	LOSARTAN POTASSIUM 50 mg TABLETS, USP 1000 tablets/bottle	GS017387	01/2020
60429-317-90	LOSARTAN POTASSIUM 50 mg TABLETS 90 tablets/bottle	GS017651	01/2020
60429-317-30	LOSARTAN POTASSIUM 50 mg TABLETS 30 tablets/bottle	GS017479	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS 90 tablets/bottle	GS017042	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS 90 tablets/bottle	GS017043	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS, USP 90 tablets/bottle	GS017044	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS, USP 90 tablets/bottle	GS017541	01/2020

Note – "GSMS FG" refers to Golden State Medical Supply Finished Goods.

Patients wishing to return product may contact Teva's product recall processor to obtain instructions and a return kit for returning their medication:

- Contact Inmar at 877-789-2065 (Hours of operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: tevarecalls@inmar.com (mailto:tevarecalls@inmar.com).
- Inmar will provide the materials needed to return their medication and instructions for reimbursement.

Customers of Golden State Medical Supply, Inc. may contact them at:

- Call: (800) 284-8633, ext. 215
- Fax: (805) 437-7582
- Email: recalls@gsms.us (mailto:recalls@gsms.us)

Link to Original Recall (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-and-100-mg)

Company Contact Information

Consumers:

Teva Medical Information

888-838-2872, option 3, then, option 4

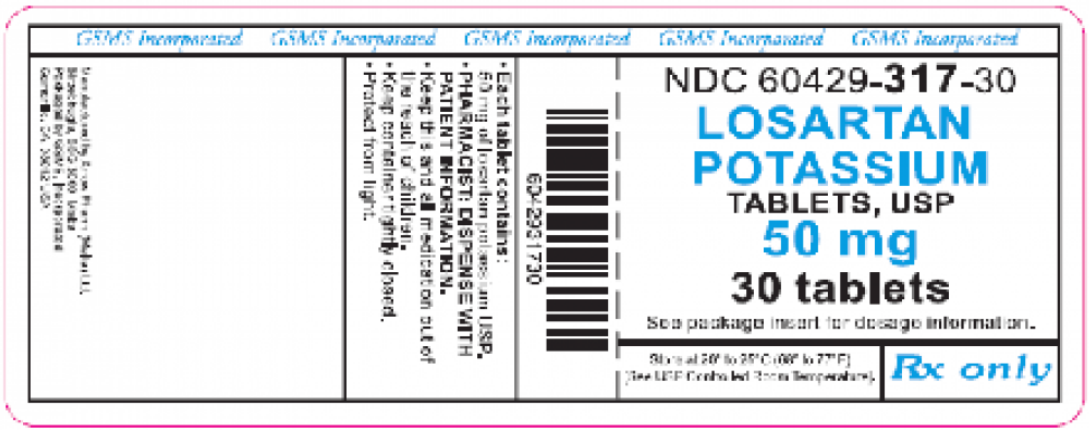
druginfo@tevapharm.com (mailto:druginfo@tevapharm.com)

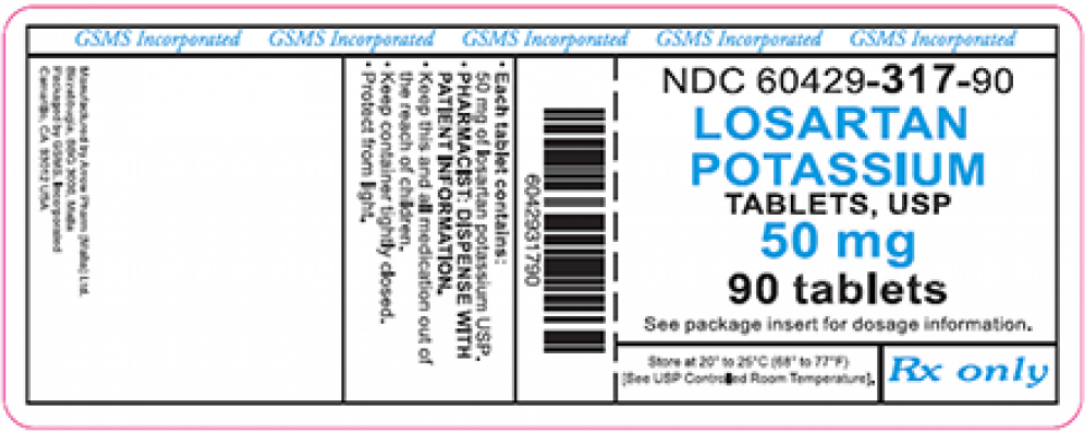
Media:

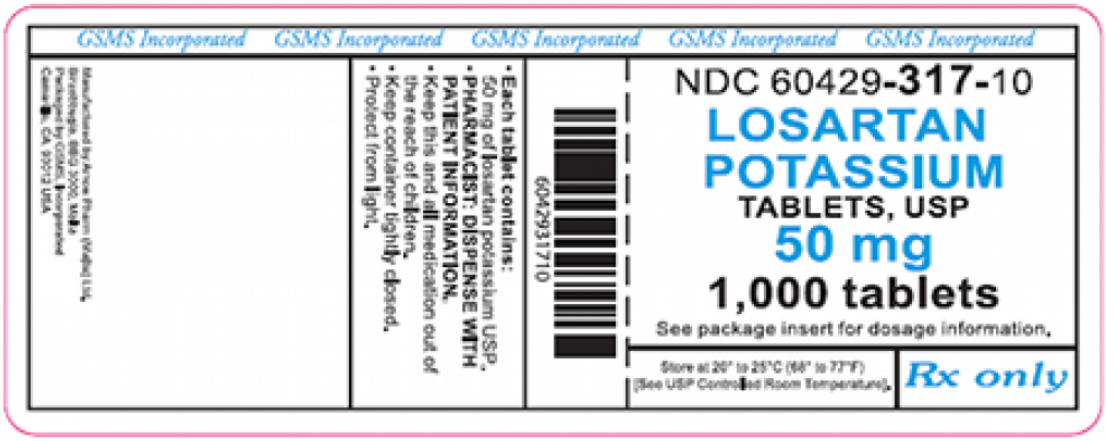
Eric Rubin, Kelley Dougherty

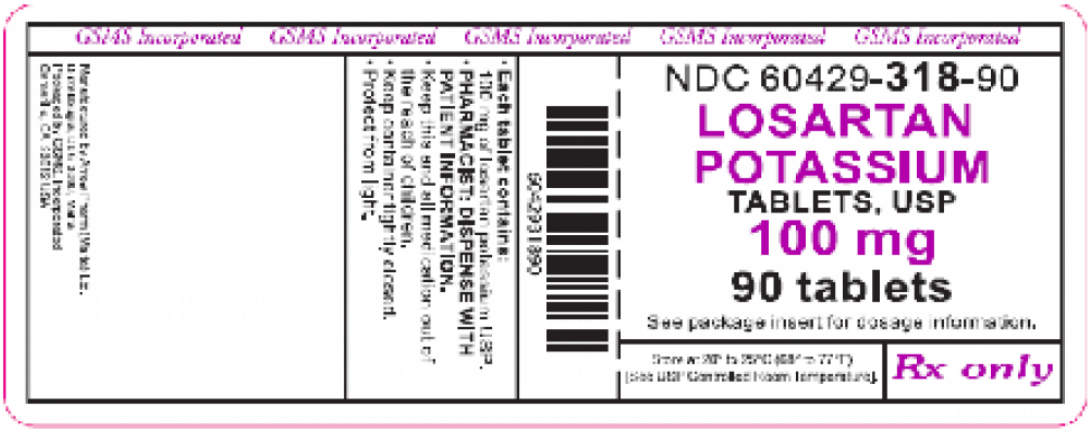
973-265-3759, 973-658-0237

Product Photos


GSMS Incorporated
• Each tablet contains: 50 mg of losartan potassium USP.
• PHARMACIST: DISPENSE WITH PATIENT INFORMATION.
• Keep this and all medication out of the reach of children.
• Keep container tightly closed.
• Protect from light.
60429317730
NDC 60429-317-30
LOSARTAN POTASSIUM
TABLETS, USP
50 mg
30 tablets
See package insert for dosage information.
Rx only


GSMS Incorporated
• Each tablet contains: 50 mg of losartan potassium USP.
• PHARMACIST: DISPENSE WITH PATIENT INFORMATION.
• Keep this and all medication out of the reach of children.
• Keep container tightly closed.
• Protect from light.
60429317790
NDC 60429-317-90
LOSARTAN POTASSIUM
TABLETS, USP
50 mg
90 tablets
See package insert for dosage information.
Rx only


GSMS Incorporated
• Each tablet contains: 50 mg of losartan potassium USP.
• PHARMACIST: DISPENSE WITH PATIENT INFORMATION.
• Keep this and all medication out of the reach of children.
• Keep container tightly closed.
• Protect from light.
60429317710
NDC 60429-317-10
LOSARTAN POTASSIUM
TABLETS, USP
50 mg
1,000 tablets
See package insert for dosage information.
Rx only


GSMS Incorporated
• Each tablet contains: 100 mg of losartan potassium USP.
• PHARMACIST: DISPENSE WITH PATIENT INFORMATION.
• Keep this and all medication out of the reach of children.
• Keep container tightly closed.
• Protect from light.
60429319190
NDC 60429-318-90
LOSARTAN POTASSIUM
TABLETS, USP
100 mg
90 tablets
See package insert for dosage information.
Rx only

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls)