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ASIA EDITION

Teva Pharmaceuticals issues voluntary nationwide recall of Losartan Potassium

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Teva promptly notified Golden State Medical Supply of the presence of the impurity in Hetero's API and Teva will recall thirty-five (35) lots of bulk Losartan Potassium tablets sold to that company.

Teva Pharmaceuticals USA, Inc. has initiated a voluntary recall in the United States, to the patient level, of 35 lots of bulk Losartan Potassium USP Tablets (6 lots of 25 mg strength and 29 lots of 100 mg strength). This recall is due to the detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) – found in six lots of active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited 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 cannot be ruled out.

Losartan Potassium is indicated for the treatment of hypertension, hypertensive patients with left ventricular hypertrophy, and nephropathy in Type 2 diabetic patients. The lots were sold exclusively to Golden State Medical Supply of Camarillo, California. Golden State Medical Supply packages this bulk product under its own label and distributes in retail bottles of 30, 90, and 1000 tablets.

To date, Teva has not received any reports of adverse events related to the lots being recalled.

No other Teva Losartan Potassium finished drug products have been identified, in the United States, containing API above the interim specification levels set for NMBA.

The affected Losartan Potassium tablets being recalled are described as:

- Losartan Potassium tablets, USP 25 mg, are light-green, film-coated, teardrop-shaped biconvex tablet with "LK 25" 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 of the presence of the impurity in Hetero's API and Teva will recall thirty-five (35) lots of bulk Losartan Potassium tablets sold to that company. The tablets, which have been packaged and sold by Golden State Medical Supply, will be recalled from their customers and patients. Distributors and retailers that have the

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.

Patients taking Losartan Potassium tablets are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding 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.