Losartan Potassium Tablets USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP – Torrent Pharmaceutical Limited

On April 18, 2019 the U.S. Food and Drug Administration (FDA) announced that Torrent Pharmaceutical Limited expanded its recall for Losartan Potassium tablets, USP and Losartan Potassium/Hydrochlorothiazide tablets, USP due to the detection of trace amounts of unexpected impurity found in active pharmaceutical ingredient (API) manufactured by Hetro Labs Limited. The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA). Torrent is only recalling lots of losartan-containing products that contain N-Methylnitrosobutyric acid (NMBA) above the accepted daily intake levels released by the FDA.

Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Losartan potassium and hydrochlorothiazide tablets, USP are used to treat hypertension and hypertensive patients with Left Ventricular Hypertrophy.

Patients who are taking Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

Patients with medical questions regarding the recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at: 1-800-912-9561 Monday-Friday 8:00 AM – 5:00 PM (EST). Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.