Losartan Potassium Hydrochlorothiazide - Macleods Pharmaceuticals Limited

On February 22, 2019 the U.S. Food and Drug Administration (FDA) announced that Macleods Pharmaceuticals Limited is voluntarily recalling one lot of Losartan Potassium Hydrochlorothiazide Tablets, USP 100mg/25mg. This product is being recalled due to the detection of trace amounts of an unexpected impurity, N-nitrosodiethylamine (NDEA). This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC).

Losartan Potassium Hydrochlorothiazide combination tablets are indicated for the treatment of hypertension and hypertensive patients with Left Ventricular Hypertrophy. Patients who are on Losartan Potassium/Hydrochlorothiazide combination tablets 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. The product can be identified as Losartan Potassium Hydrochlorothiazide, 100 mg/25 mg tablets, NDC 33342-0052-10, Lot number BLM715A; Exp. Date 07/2019.

Patients with questions regarding this recall can contact Qualanex via email at recall@equalanex.com or call at 1-888-280-2042 Monday-Friday 7:00 AM – 4:00 PM (CST). Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Losartan Potassium Hydrochlorothiazide.