Losartan Potassium Hydrochlorothiazide Tablet – Sandoz, Inc.

On November 8, 2018 the U.S. Food and Drug Administration (FDA) announced that Sandoz, Inc. is voluntarily recalling one lot of Losartan Potassium Hydrochlorothiazide Tablets, USP 100mg/25mg. This product is being recalled due to the trace amount of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Losartan. 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 tablets are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. The product can be identified as Losartan Potassium Hydrochlorothiazide, 100 mg/25 mg tablets, NDC 0781-5207-10, Lot number JB8912; Exp. Date 06/2020.

Patients with questions regarding this recall can contact Sandoz Inc. at 1-800-525-8747 Monday-Friday 8:30 AM – 5:00 PM (EST) or email usdrugsafety.operations@novartis.com. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Losartan Potassium Hydrochlorothiazide should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. 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.