November 14,2018

COM-2018-022

Dear provider of pharmaceutical services,

Recall: Voluntary recall of Losartan Potassium and Hydrochlorothiazide

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform that on November 8, 2018 the US Food and Drug Administration (FDA) issued a statement notifying the voluntary retirement of one lot of Losartan Potassium and Hydrochlorothiazide 100mg/25mg manufactured by Lek Pharmaceuticals dd, Ljubljana, Slovenia. The recall was made due to detection of trace amounts of NDEA (N-Nitrosodiethylamine) impurity found in the active pharmaceutical ingredient (API) Losartan manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. Sandoz Inc. 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). The lot affected is detailed on Table 1.

Table 1. Affected lots Losartan Potassium and Hydrochlorothiazide

Product	Affected Lot	Expiration date	NDC
Losartan Potassium Hydrochlorothiazide, 100 mg/25 mg tablets, 1000-count	JB8912	06/2020	0781-5207-10

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. It is important that pharmacy contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should not discontinue taking the medication without a doctor's permission.
3. For questions regarding this recall please visit FDA website or can contact Sandoz Inc. at 1-800-525-8747 Monday-Friday 8:30 AM – 5:00 PM (EST) or email usdrugsafety.operations@novartis.com

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm625492.htm

Department of Clinical Pharmacy

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