December 24, 2018

COM-2018-028

Recall: Voluntary recall of Losartan Potassium Tablets

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on December 20, 2018 the US Food and Drug Administration (FDA) issued a statement notifying that Torrent Pharmaceuticals Limited is voluntarily recalling 2 lots of Losartan potassium tablets, USP. The recall was made because these lots does not meet safety standards due to the presence of the impurity N-nitrosodiethylamine (NDEA), a substance that could cause cancer. The products affected by the recall are detailed on Table 1.

Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles	BO31C016	04/2019	13668-115-30
LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles	BO31C016	04/2019	13668-115-90
LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C005	04/2019	13668-115-10

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. 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. Contact Qualanex at 1-888-280-2040 for any questions regarding recalled product. Normal business hours are Monday through Friday 8 a.m. to 9 p.m. EST.

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm628966.htm

Department of Clinical Pharmacy

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