January 3, 2019

COM-2019-001

Recall: Torrent Pharmaceuticals Limited Expands Voluntary Nationwide 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 January 3, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Torrent Pharmaceuticals Limited expanded the voluntarily recall 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
LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C004	04/2019	13668-115-10
LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3C040	10/2019	13668-115-10
LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E049	05/2021	13668-115-10
LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E050	05/2021	13668-115-10
LOSARTAN POTASSIUM TAB, USP 50mg,30count bottles	4L67C035	10/2019	13668-409-30
LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C035	10/2019	13668-409-30
LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C036	10/2019	13668-409-30
LOSARTAN POTASSIUM TAB, USP 50mg,1000-count bottles	4O50C005	11/2019	13668-409-10
LOSARTAN POTASSIUM TAB, USP	4O49C013	09/2019	13668-113-90

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
25mg,90count bottles			

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/ucm629261.htm

Department of Clinical Pharmacy

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