July 2, 2019

COM-2019-029

Macleods Pharmaceutical Limited Issues Voluntary Nationwide Consumer Level Recall of Losartan Potassium 50mg and Losartan Potassium/Hydrochlorothiazide combination Tablets 50mg/12.5mg, 100mg/12.5mg and 100mg/25mg due to detection of NMBA (N-Nitroso-N- Methyl-4-aminobutyric acid) Impurity

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 June 26, 2019 the US Food and Drug Administration (FDA) issued a statement that Macleods Pharmaceuticals Limited has initiated a voluntary recall, to the patient level, of 32 lots of Losartan Potassium USP Tablets (single or in combination with Hydrochlorothiazide) manufactured by Hetero Labs Limited. This recall is due to the detection of an impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA); a potential human carcinogen that is above FDA's interim acceptable exposure limit of 9.82 ppm. The affected products of the recall are detailed on Table 1.

Table 1. Losartan Products

NDC	Product	Affected Lot & Expiration Date
33342-045-10	Losartan Potassium.Tablets USP 50mg 90ct	BLl711A- Nov-19
33342-045-44	Losartan Potassium Tablets USP 50mg 1000ct	BLl710A- Nov-19
33342-050-10	Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/ 12.5	BLK719A- Sep-19; BLK720A-Sep-19; BLK721A-Sep-19; BLK722A-Sep-19; BLK723A-Sep-19; BLK724A-Sep-19; BLK725A-Oct-19; BLK726A-Oct-19; BLK804A-Jan-20; BLK806A-Jan-20; BLK825A-Oct-21; BLK826A-Oct-21

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Table 1. Losartan Products (cont.)

NDC	Product	Affected Lot & Expiration Date
33342-051-10	Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 12.5 mg	BLL801A-Dec-19; BLL802A-Dec-19; BLL803A-Dec-19
33342-052-10	Losartan Potassium and Hydrochlorothiazide Tablets 100 mg/ 25 mg	BLM716A-Jul-19; BLM717A-Jul-19; BLM719A-Aug-19; BLM720A-Aug-19; BLM721A-Sep-19; BLM722A-Sep-19; BLM723A-Oct-19; BLM724A-Oct-19; BLM725A-Oct-19; BLM726A-Nov-19; BLM802A-Dec-19; BLM803A-Dec-19; BLM825A-Sep-21; BLM826A-Sep-21; BLM827A-Sep-21

Note: *Macleods is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.*

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop 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. Consumers with medical questions regarding this recall or to report an adverse event can contact Macleods Pharmaceuticals Limited at 855-926-3384 (8:00 am - 5:00 pm EST).
4. General questions regarding the return of this product, please contact Qualanex via email at recall@qualanex .com or call 888-280-2046 (7:00 am to 4:00 pm CST Monday to Friday)

For additional information, visit: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/macleods-pharmaceutical-limited-issues-voluntary-nationwide-consumer-level-recall-losartan-potassium

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