September 24, 2019

COM-2019-040

Updated Recall: Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium / Hydrochlorothiazide 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 September 23, 2019, the U.S. Food and Drug Administration (FDA) issued a statement notifying that Torrent Pharmaceuticals Limited is recalling losartan and losartan Potassium / hydrochlorothiazide tablets to the patient level. The reason is due to traces of an impurity called N - Methylnitrosobutyric acid (NMBA) found in the active pharmaceutical ingredient. This notification applies only to those lots containing NMBA.

The affected lots by the recall are detailed in Table 1.

Table 1: Affected Products of Losartan Potassium Tablet and Losartan Potassium / Hydrochlorothiazide tablets

NDC	Product	Count	Batch #	Expiration date
13668-409-10	Losartan Potassium Tablets, USP 50mg	1000	4DU2E009	12/31/2020
13668-115-90	Losartan Potassium Tablets, USP 100mg	90	4DU3E009	12/31/2020
13668-115-10	Losartan Potassium Tablets, USP 100mg	1000	4DU3E018	02/28/2021
13668-116-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg	90	BEF7D051	11/30/2020
13668-118-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 100mg/25mg	90	4P04D007	07/31/2020

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. Questions regarding this recall, refer to the contact information below:
    a. Medical inquiries: Torrent Pharmaceuticals Limited phone is 1-800-912-9561 (8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week) online address: Medinfo.Torrent@apcerls.com

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

b. Returning process: Qualanex phone is 1-888-280-2040 (8:00 am - 9:00 pm Eastern Time)

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

a. Online: www.fda.gov/medwatch/report.htm
b. Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-0

Clinical Department

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