

The United States: Torrent Pharmaceuticals Limited expands voluntary nationwide recall of Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP

The US Food and Drug Administration (FDA) announces that Torrent Pharmaceuticals Limited is expanding its recall for Losartan Potassium Tablets USP and Losartan Potassium / hydrochlorothiazide tablets, USP, to the consumer level due to the detection of trace amounts of an unexpected impurity while testing the below finished product batches manufactured utilizing active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited using the old Route of Synthesis. The recall is expanded to include an additional 3 lots of Losartan Potassium Tablets USP and 2 lots of Losartan Potassium/Hydrochlorothiazide Tablets, USP.

The impurity detected is N-Methylnitrosobutyric acid (NMBA). Torrent is only recalling lots of losartan-containing products that contain N-Methylnitrosobutyric acid (NMBA) above the acceptable daily intake levels released by the FDA.

Patients who are taking Losartan Potassium Tablets, USP and Losartan Potassium / Hydrochlorothiazide Tablets, USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The product/lots included in the expanded recall are listed below:

NDC	Product Name, Strength and Package Count	Batch Number	Expiration Date
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E009	12/31/2020
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E009	12/31/2020
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3D018	02/28/2021
13668-116-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D051	11/30/2020
13668-118-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count.	4P04D007	07/31/2020

Please refer to the following website in FDA for details:

<http://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-0>

In Hong Kong, the above products are not registered pharmaceutical products.

Currently in Hong Kong, there are 243 registered pharmaceutical products containing valsartan (82 products), candesartan (19 products), irbesartan (62 products), losartan (63 products) and olmesartan (17 products). All products are prescription-only medicines.

Regarding impurities in sartan-containing products, a public announcement was first issued on 6 Jul 2018, and letters to inform local healthcare professionals were issued by the Department of Health (DH) on 6 Jul 2018, 9 Jul 2018, 25 Jul 2018 and 3 Aug 2018. Related news was also previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 6 Jul 2018, with the latest update posted on 27 June 2019.

Regarding the announcements issued by various overseas drug regulatory authorities on the detection of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) in sartan-containing products, the following 5 valsartan products and 1 irbesartan product were affected and recalled from the Hong Kong market on 6 Jul 2018 and 20 Dec 2018 respectively: HK-61786, HK-61787, HK-61784, HK-61785, HK-60794 and HK-63378. The DH noted that these recalls were completed.

The DH had collected samples of sartan-containing products in the local market for analysis. No NDMA and NDEA were detected.

Regarding the announcements issued by various overseas drug regulatory authorities on the detection of NMBA in losartan, the DH endorsed the recall of 4 losartan products (HK-61932, HK-61933, HK-62634 and HK-62635) from the local market as a precautionary measure due to the potential for NMBA in the products on 11 Mar 2019. The DH noted that the recall was completed.

So far, the DH has received 18 cases of adverse drug reaction related to valsartan, candesartan, irbesartan, losartan and olmesartan. None of them is concluded to be related to the presence of impurities such as NDMA, NDEA and/or NMBA. The DH will keep vigilant on any safety updates on detection of impurities in sartan-containing products issued by overseas regulatory authorities.

Patients who are taking sartan-containing products should not stop taking the medicines, but should seek advice from their healthcare professionals as soon as possible for proper arrangement.

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