

## Torrent Pharmaceuticals Recalls 14 Lots of Valsartan

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**The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.**



Torrent Pharmaceuticals Limited is voluntarily recalling 14 lots of Valsartan/Amlodipine/HCTZ tablets to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Valsartan is used to control high blood pressure and for the treatment of heart failure. In combination with amlodipine plus hydrochlorothiazide, it is used to control high blood pressure. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.