



Torrent – Recall of Amlodipine/Valsartan/Hydrochlorothiazide

- On August 17, 2018, the [FDA announced](#) a voluntary, consumer-level recall of several lots of Torrent’s [amlodipine/valsartan/hydrochlorothiazide \(HCTZ\)](#) tablets due to the presence of an impurity, N-nitrosodimethylamine (NDMA).
- The recalled amlodipine/valsartan/HCTZ tablets were distributed nationwide.

Product Description	NDC#	Lot#
Amlodipine/valsartan/ HCTZ 10 mg/320 mg/25 mg tablets	13668-325-30	BBX2D025 (11/2019); BBX2D026 (11/2019); BBX2E001 (1/2020); BBX2E002 (1/2020); BBX2E003 (1/2020); BBX2E004 (1/2020); BBX2E005 (1/2020)
Amlodipine/valsartan/ HCTZ 10 mg/160 mg/25 mg tablets	13668-328-30	BBX9D004 (11/2019); BBX9E001 (1/2020)
Amlodipine/valsartan/ HCTZ 5 mg/160 mg/12.5 mg tablets	13668-326-30	BBY1E001 (12/2019); BBY1E003 (3/2020)
Amlodipine/valsartan/ HCTZ 10 mg/160 mg/12.5 mg tablets	13668-327-30	BBY2E001 (3/2020)
Amlodipine/valsartan/ HCTZ 5 mg/160 mg/25 mg tablets	13668-329-30	BBY4D004(11/2019); BBY4E001 (1/2020)

- Valsartan is used to control high blood pressure and for the treatment of heart failure. In combination with amlodipine plus HCTZ, it is used to control high blood pressure.
- Consumers should contact their healthcare provider for further guidance and potential change of treatment before they stop taking amlodipine/valsartan/HCTZ. Pharmacies and healthcare facilities that have the recalled product should stop using and dispensing the product immediately.
- Patients with questions regarding this recall can contact Torrent at **1-800-912-9561**. Patients should contact their healthcare provider if they have experienced any problems that might be related to taking or using the recalled amlodipine/valsartan/HCTZ.
- On July 13th, the [FDA initiated](#) a series of announcements regarding the recall of certain batches of valsartan and valsartan-HCTZ tablets because of unacceptable levels of NDMA.
- The FDA continues to maintain a [list of drugs included in the recall](#) and a [list of drugs not included in the recall](#). These lists were last updated on August 20, 2018.
 - In addition to the Torrent products, one lot of valsartan 320 mg repackaged by Preferred Pharmaceuticals was added to the list of recalled products.

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- Prior Clinical News Summaries summarizing the valsartan recalls were released [July 17th](#), [July 19th](#), [July 27th](#), [July 30th](#), [August 3rd](#), [August 9th](#), and [August 14th](#).



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