Torrent – Recall of Valsartan-Containing Products

- On August 21, 2018, the FDA announced an update to the voluntary, consumer-level recall of Torrent's amlodipine/valsartan/hydrochlorothiazide (HCTZ), amlodipine/valsartan and valsartan tablets due to the presence of an impurity, N-nitrosodimethylamine (NDMA).

- From the initial FDA announcement on August 17, 2018, the recall has been expanded to include all lots of amlodipine/valsartan/HCTZ, amlodipine/valsartan, and valsartan tablets.

- The recalled valsartan-containing tablets were distributed nationwide.

Product Description	NDC#	Lot#
Amlodipine/valsartan/HCTZ 10 mg/320 mg/25 mg	13668-325-30	All unexpired lots
Amlodipine/valsartan/HCTZ 10 mg/160 mg/25 mg	13668-328-30	
Amlodipine/valsartan/HCTZ 5 mg/160 mg/12.5 mg	13668-326-30	
Amlodipine/valsartan/HCTZ 10 mg/160 mg/12.5 mg	13668-327-30	
Amlodipine/valsartan/HCTZ 5 mg/160 mg/25 mg	13668-329-30	
Amlodipine/valsartan 5 mg/160 mg	13668-207-30	
Amlodipine/valsartan 10 mg/160 mg	13668-206-30	
Amlodipine/valsartan 10 mg/320 mg	13668-204-30	
Amlodipine/valsartan 5 mg/320 mg	13668-205-30	
Valsartan 160 mg	13668-069-90	
Valsartan 320 mg	13668-070-90	
Valsartan 80 mg	13668-068-90	

- Valsartan is used to control high blood pressure and for the treatment of heart failure. In combination with amlodipine plus HCTZ or in combination with amlodipine alone, 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 their valsartan-containing prescription. 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 valsartan-containing prescription.

- 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. Note that not all of the recalled Torrent products are included in the list of drugs included in the recall.

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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, August 14th, and August 20th.