



Aurobindo Pharma – Recall of Valsartan-Containing Products

- On December 31, 2018, [Aurobindo Pharma announced](#) a voluntary, consumer-level recall of several lots of [amlodipine/valsartan](#), [valsartan/hydrochlorothiazide \(HCTZ\)](#), and [valsartan](#) tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine (NDEA), found in the finished drug product.
- NDEA 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 classification.
 - To date, Aurobindo Pharma has not received any reports of adverse events related to this recall.
 - Refer to the [FDA site](#) for updates regarding angiotensin II receptor blocker recalls.
- The recalled products were distributed nationwide. Refer to the Aurobindo Pharma announcement for the list of specific recalled NDC numbers and lot numbers.
- Valsartan is used to control high blood pressure and for the treatment of heart failure. Valsartan in combination with HCTZ or amlodipine is used for the treatment of high blood pressure.
- Patients taking amlodipine/valsartan combination tablets, valsartan/HCTZ combination tablets, or valsartan tablets are advised to continue taking their medication and to contact their pharmacist or physician for advice on alternative treatment. The risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled valsartan-containing product.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

For more information regarding this recall, contact Aurobindo Pharma at **1-866-850-2876** or Inmar\CLS-Medturn at **1-877-208-2407** for general questions regarding return of the product.



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