Aurobindo Pharma – Recall of valsartan-containing products

- On February 25, 2019, Aurobindo Pharma announced a voluntary, consumer-level recall of several lots of valsartan and amlodipine/valsartan tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine (NDEA).

- 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.

  — Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.

Product Description	NDC#	Lot# (Expiration Date)
Amlodipine and Valsartan Tablets 10mg/160mg	65862-0739-30	VFSA17007-A (10/2019)
Valsartan Tablets 160 mg	52343-0124-90	472180005B (02/2020); 472180011A (04/2020); 472180012A (04/2020)
	65862-0572-90	472180001A (01/2020); 472180002A (01/2020); 472180003A (01/2020); 472180004A (01/2020); 472180007A (03/2020); 472180008A (03/2020); 472180009A (03/2020); 472180010A (03/2020); 472180013A (04/2020); 472180014A (04/2020)
Valsartan Tablets 320mg	65862-0573-90	473180006A (03/2020); 473180016A (05/2020); 473180004A (02/2020); 473170019A (10/2019); 473180005A (02/2020); 473180017A (05/2020)
	52343-0125-90	473180020B1 (07/2020); 473180007A (03/2020); 473180008A (03/2020); 473180011A (04/2020)

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Valsartan Tablets 40mg	65862-0570-30	470180032A (05/2020); 470180008A (02/2020); 470180014A (03/2020); 470180016A (03/2020)
	52343-0122-30	470180010A (02/2020); 470180012A (03/2020); 470170038A (10/2019)
Valsartan Tablets 80mg	65862-0571-90	471180005A (02/2020); 471170015A (09/2019); 471180004A (02/2020)
	52343-0123-90	471170019A (10/2019); 471180006A (03/2020); 471180007A (03/2020); 471180016A (05/2020)

- Valsartan is used to control high blood pressure and for the treatment of heart failure. Valsartan in combination with amlodipine is used for the treatment of 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 or amlodipine/valsartan should continue taking their medication, as 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 or amlodipine/valsartan.
- 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 Inmar (appointed company for Aurobindo) at **1-877-208-2407**.

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