



Drug Recall

DATE OF RECALL: February 28, 2019

DRUG NAME: Valsartan and Valsartan Amlodipine Tablets

RECALLING FIRM: AurobindoPharma USA, Inc

REASON FOR RECALL: This recall was issued due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), 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.

FDA LINK: <https://www.fda.gov/Safety/Recalls/ucm632442.htm>

OTHER DETAILS: See FDA link.

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Valsartan 40 mg Tablets 30 count bottle	52343-0122-30	470170038A 470180010A 470180012A	10/2019 02/2020 03/2020
Valsartan 80 mg Tablets 90 count bottle	52343-0123-90	471170019A 471180006A 471180007A 471180016A	10/2019 03/2020 03/2020 05/2020
Valsartan 160 mg Tablets 90 count bottle	52343-0124-90	472180005B 472180011A 472180012A	02/2020 04/2020 04/2020
Valsartan 320 mg Tablets 90 count bottle	52343-0125-90	4731800007A 4731800008A 473180011A 473180020B1	03/2020 03/2020 04/2020 07/2020
Valsartan 40 mg Tablets 30 count bottle	65862-0570-30	470180008A 470180014A 470180016A 470180032A	02/2020 03/2020 03/2020 05/2020
Valsartan 80 mg Tablets 90 count bottle	65862-0571-90	471170015A	09/2019



Valsartan 80 mg Tablets 90 count bottle	65862-0571-90	471180004A 471180005A	02/2020 02/2020
Valsartan 160 mg Tablets 90 count bottle	65862-0572-90	472180001A 472180002A 472180003A 472180004A 472180007A 472180008A 472180009A 472180010A 472180013A 472180014A	01/2020 01/2020 01/2020 01/2020 03/2020 03/2020 03/2020 03/2020 04/2020 04/2020
Valsartan 320 mg Tablets 90 count bottle	65862-0573-90	473180004A 473180005A 473180006A 473180017A 473170019A 473180016A	02/2020 02/2020 03/2020 05/2020 10/2019 05/2020
Amlodipine and Valsartan 10mg/160 mg Tablets 30 count bottle	65862-0739-30	VFSA17007-A	10/2019