January 3, 2019

**COM-2019-002**

# Recall: Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Consumer Level Recall of 80 Lots of Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on December 31, 2018 the US Food and Drug Administration (FDA) issued a statement notifying that Aurobindo Pharma USA, Inc. is voluntarily recalling of Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP. The recall was made because these lots does not meet safety standards due to the presence of the impurity N-nitrosodiethylamine (NDEA), a substance that could cause cancer. The products affected by the recall are detailed on Table 1.

**Table 1. Affected products**

| Product | Affected Lot | Expiration date | NDC |
|---|---|---|---|
| Amlodipine and Valsartan Tablets USP5mg/160mg | VESA17013-A | 10/2019 | 65862-737-30 |
| Amlodipine and Valsartan Tablets USP5mg/160mg | VESA17014-A | 10/2019 | 65862-737-30 |
| Amlodipine and Valsartan Tablets USP5mg/160mg | VESA18001-A | 12/2019 | 65862-737-30 |
| Amlodipine and Valsartan Tablets USP5mg/160mg | VESA18002-A | 12/2019 | 65862-737-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA17008-A | 10/2019 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA17010-A | 10/2019 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA18002-A | 01/2020 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA18003-A | 01/2020 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA18007-A | 03/2020 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA18008-A | 03/2020 | 65862-739-30 |



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**Table 1. Affected products**

| Product | Affected Lot | Expiration date | NDC |
|---|---|---|---|
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA17008-A | 05/2019 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA17014-A | 10/2019 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA17015-A | 10/2019 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA17016-A | 10/2019 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA17017-A | 10/2019 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA18002-A | 01/2020 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP10mg /320mg | VKSA18004-A | 01/2020 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17012-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17013-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17014-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17015-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17016-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP5mg /320mg | VMSA17017-A | 11/2019 | 65862-738-30 |
| Amlodipine and Valsartan Tablets USP10mg/160mg | VFSA17009-A | 10/2019 | 65862-739-30 |
| Amlodipine and Valsartan Tablets USP 10mg /320mg | VKSA18005-A | 03/2020 | 65862-740-30 |
| Amlodipine and Valsartan Tablets USP 10mg /320mg | VKSA18001-A | 01/2020 | 65862-740-30 |
| Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg | HRSA17033-A | 10/2020 | 65862-550-90 |
| Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg | HRSA17034-A | 10/2020 | 65862-550-90 |
| Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg | HRSA17035-A | 10/2020 | 65862-550-90 |
| Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg | HRSA17036-A | 10/2020 | 65862-550-90 |
| Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg | HRSA17037-A | 10/2020 | 65862-550-90 |



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**Table 1. Affected products**

| Product | Affected Lot | Expiration date | NDC |
|---|---|---|---|
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17033-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17034-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17035-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17036-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17040-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17041-A | 11/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17042-A | 11/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg | HTSA17043-A | 11/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17049-A | 08/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17054-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17055-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17056-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17057-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17058-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17059-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17060-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17062-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17066-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17067-A | 11/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17068-A | 11/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17069-A | 11/2020 | 65862-551-90 |



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**Table 1. Affected products**

| Product | Affected Lot | Expiration date | NDC |
|---|---|---|---|
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18001-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18002-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18003-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18003-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18004-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18005-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18006-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB18007-A | 12/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg | HVSA17011-A | 11/2020 | 65862-547-90 |
| | | | |
| Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg | HVSA17012-A | 11/2020 | 65862-547-90 |
| Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg | HVSA18001-A | 12/2020 | 65862-547-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17023-A | 08/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17036-A | 11/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17037-A | 11/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17038-A | 11/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17039-A | 11/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB17040-B | 11/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB18001-A | 12/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB18002-A | 12/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB18003-A | 12/2020 | 65862-549-90 |
| Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg | HVSB18004-A | 12/2020 | 65862-549-90 |



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**Table 1. Affected products**

| Product | Affected Lot | Expiration date | NDC |
|---|---|---|---|
| Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg | HTSA17037-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg | HTSA17039-A | 10/2020 | 65862-548-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17063-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17064-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg | HTSB17065-A | 10/2020 | 65862-551-90 |
| Valsartan and Hydrochlorothiazide Tablets USP & 320/25mg | HTSB18029-A | 03/2021 | 65862-551-90 |
| Valsartan Tablets USP 320mg | VUSD17008-A | 07/2019 | 65862-573-90 |
| Valsartan Tablets USP 320mg | VUSD17009-A | 09/2019 | 65862-573-90 |

**The Pharmacy must:**

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should not discontinue taking the medication without a doctor's permission.
3. Contact Inmar\CLS-Medturn at 1-877-208-2407 or email rxrecalls@inmar.com. Normal business hours are 9:00 am -5:00 pm Eastern Time.

**For additional information visit:**

https://www.fda.gov/Safety/Recalls/ucm629213.htm

Department of Clinical Pharmacy



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