Mylan – Recall of Valsartan-Containing Products

- On November 20, 2018, Mylan announced a voluntary, consumer-level recall of several lots of valsartan, amlodipine/valsartan, and valsartan/HCTZ tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient (API) manufactured by Mylan Laboratories Limited.

- 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.

- These products were distributed in the U.S. between March 2017 and November 2018. The recalled batches are as follows:

Product Description	NDC#	Lot# (Expiration Date)
Amlodipine/valsartan 5 mg/160 mg tablets	0378-1721-93	3066051 (3/2019)
Amlodipine/valsartan 10 mg/160 mg tablets	0378-1722-93	3079500 (1/2020)
Amlodipine/valsartan 10 mg/320 mg tablets	0378-1724-93	3061986 (11/2018); 3079709 (1/2020); 3077618 (11/2019); 3079708 (1/2020)
Valsartan 40 mg tablets	0378-5807-93	3061169 (11/2018)
Valsartan 80 mg tablets	0378-5813-77	3063782 (1/2019)
Valsartan 160 mg	0378-5814-77	3071352 (7/2019)
Valsartan 320 mg tablets	0378-5815-77	3081499 (3/2020); 3080009 (2/2020); 3080010 (2/2020); 3079205 (1/2020)
Valsartan/HCTZ 320 mg/25 mg tablets	0378-6325-05	3084886 (2/2019); 3093804 (12/2019)

- 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 should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on a valsartan-containing product 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-containing product.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

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- For more information regarding this recall, contact Mylan at **1-800-796-9526** or Stericycle at **1-888-406-9305**.