Teva – Recall of Valsartan-Containing Products

- On November 27, 2018, Teva announced a voluntary, consumer-level recall of all lots of amlodipine/valsartan, and amlodipine/valsartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient manufactured by Teva India.

- 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, Teva has not received any reports of adverse events signaling a potential link or exposure to valsartan.

- The recalled products were distributed nationwide. Refer to the Teva announcement for the list of specific recalled NDC numbers and lot numbers.

- Amlodipine/valsartan combination tablets and amlodipine/valsartan/HCTZ combination tablets are used for the treatment of high blood pressure.

- Patients taking amlodipine/valsartan combination tablets or amlodipine/valsartan/HCTZ combination 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 Teva medical information at **1-888-838-2872**.