Major, Solco Healthcare, and Teva – Recall of Valsartan and Valsartan/Hydrochlorothiazide Products

- On July 16, 2018, Teva announced a voluntary recall of valsartan and valsartan/hydrochlorothiazide (HCTZ) tablets due to an impurity, N-nitrosodimethylamine (NDMA).
    - Products manufactured by Solco Healthcare and Major are also impacted by the recall.
- The recalled products are as follows:

Manufacturer	Product Name
Solco Healthcare	Valsartan tablets 40 mg, 80 mg, 160 mg, and 320 mg tablets
	Valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg tablets
Major	Valsartan 80 mg and 160 mg tablets
Teva	Valsartan 40 mg, 80 mg, 160 mg, and 320 mg tablets
	Valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg tablets

- Valsartan and valsartan/HCTZ are indicated for the treatment of hypertension.
    - Valsartan is also indicated for the treatment of heart failure (NYHA class II – IV), and to reduce cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction.
- NDMA is classified as a probable human carcinogen. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.
    - The FDA review is ongoing and has included investigating the levels of NDMA in the recalled products, assessing the possible effect on patients who have been taking them, and what measures can be taken to reduce or eliminate the impurity from future batches produced by the company.
- FDA recommendations:
    - Patients should contact their healthcare professional if their medicine is included in this recall to discuss their treatment, which may include another valsartan product not affected by this recall or an alternative treatment option.
    - Patients taking the recalled valsartan-containing products should continue taking their medicine until they have a replacement product.
    - Patients should contact their physician or healthcare provider if they believe they have experienced any problem that may be related to using the recalled product.

Continued . . .

- For further information regarding this recall, contact the specific company listed below.
    - Major: **1-800-616-2471**
    - Teva: **1-888-838-2872**
    - Solco Healthcare: **1-866-931-9829**