AvKARE – Recall of Valsartan/Hydrochlorothiazide

- On July 18, 2018, AvKARE announced a voluntary recall of valsartan/hydrochlorothiazide (HCTZ) tablets due to an impurity, N-nitrosodimethylamine (NDMA).
    - The recalled AvKARE products were manufactured by Teva, distributed by Actavis, and packaged into an AvKARE label.
    - Recalls by manufacturers Teva, Solco Healthcare and Major were announced earlier this week.
- The recalled products are as follows:

Manufacturer	Product Name
AvKARE	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/HCTZ is indicated for the treatment of hypertension.
- 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.
- For further information regarding this recall, contact AvKARE at **1-931-292-6222**.