AvKARE – Recall of Valsartan

- On August 14, 2018, AvKARE announced a voluntary, consumer-level recall of all unexpired lots of valsartan tablets due to the detection of an impurity, N-nitrosodimethylamine (NDMA).
- The recalled valsartan tablets were distributed beginning August 1, 2016.

Product Description	NDC#	Lot#
Valsartan 40 mg	50268-783-15; (Inner NDC: 50268-783-11)	All unexpired lots
Valsartan 80 mg	50268-784-15; (Inner NDC: 50268-784-11)	
Valsartan 160 mg	50268-785-15; (Inner NDC: 50268-785-11)	
Valsartan 320 mg	50268-786-13; (Inner NDC: 50268-786-11)	

- Valsartan is a medication commonly used to treat high blood pressure and heart failure.
- Consumers should contact their healthcare provider for further guidance and potential change of treatment before they stop taking valsartan. Pharmacies and healthcare facilities that have the recalled product should stop using and dispensing the product immediately.
- Patients with questions regarding this recall can contact AvKARE at **1-931-292-6222**. Patients should contact their healthcare provider if they have experienced any problems that might be related to taking or using the recalled valsartan.
- On July 13th, the FDA initiated a series of announcements regarding the recall of certain batches of valsartan and valsartan-hydrochlorothiazide (HCTZ) tablets because of unacceptable levels of NDMA.
- The FDA continues to maintain a list of drugs included in the recall and a list of drugs not included in the recall. Note that these lists were last updated on August 9, 2018 and the above mentioned AvKARE products have not been added to the list of drugs included in the recall.
- Prior Clinical News Summaries summarizing the valsartan recalls were released July 17th, July 19th, July 27th, July 30th, August 3rd, and August 9th.