FDA is alerting patients and health professionals to Mylan's voluntary recall of 15 lots of valsartan-containing products that contain N-nitrosodiethylamine (NDEA).

Not all Mylan valsartan-containing products distributed in the United States are being recalled. Mylan is recalling only those lots of valsartan-containing products that tested positive for NDEA above the acceptable level. The agency continues to investigate and test all angiotensin II receptor blockers (ARBs) for the presence of NDEA and N-nitrosodimethylamine (NDMA) and is taking swift action when it identifies these impurities that are above acceptable levels.

FDA has updated lists of valsartan products under recall and valsartan products not under recall.

In addition, FDA reminds patients taking this medication or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

FDA has also posted questions and answers to assist health professionals and patients.

Medication Monitor Categories:
Alerts and Recalls

Source URL: http://www.aphanet.org/alerts-and-recalls/mylan-recalls-valsartan-products-found-contain-ndea