Generic Name:
Valsartan
Trade Name:
Multiple trade names
Company:
Multiple companies
Notes:

FDA is alerting health professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

FDA?s 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.

Because valsartan is used in medicines to treat serious medical conditions, patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product. To determine whether a specific product has been recalled, patients should look at the drug name and company name on the label of their prescription bottle. If the information is not on the bottle, patients should contact the pharmacy that dispensed the medicine. If a patient is taking one of the recalled medicines, they should follow the recall instructions provided by the specific company. This information will be posted to the FDA?s website.

Patients should also contact their health professional (the pharmacist who dispensed the medication or doctor who prescribed the medication) 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.

The companies listed are recalling all lots of nonexpired products that contain the ingredient valsartan supplied by a third party. Not all valsartan-containing medicines distributed in the United States have valsartan active pharmaceutical ingredient (API) supplied by this specific company. The supplier has stopped distributing its valsartan API, and FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products.

FDA will continue to investigate this issue and provide additional information when it becomes available.

Medication Monitor Categories:
Alerts and Recalls