FDA Recalls Some Medicines Containing Valsartan Due to Impurity

Recalled products may containN-nitrosodimethylamine, a probable carcinogen.

July 18, 2018 By Food and Drug Administration (FDA)

FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity

The U.S. Food and Drug Administration is alerting health care 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 (a substance that could cause cancer) 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.

The 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.

"The FDA is committed to maintaining our gold standard for safety and efficacy. That includes our efforts to ensure the quality of drugs and the safe manner in which they're manufactured," said FDA Commissioner Scott Gottlieb, MD. "When we identify lapses in the quality of drugs and problems with their manufacturing that have the potential to create risks to patients, we're committed to taking swift action to alert the public and help facilitate the removal of the products from the market. As we seek the removal of certain drug products today, our drug shortages team is also working hard to ensure patients' therapeutic needs are met in the United States with an adequate supply of unaffected medications."

Information for Patients and Health Care Professionals

- 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 listed below, 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 care 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 below are recalling all lots of non-expired 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 the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products.

Recalled Products

Medicine	**Company**
Valsartan	Major Pharmaceuticals
Valsartan	Solco Healthcare
Valsartan	Teva Pharmaceuticals Industries Ltd.
Valsartan/Hydrochlorothiazide (HCTZ)	Solco Healthcare
Valsartan/Hydrochlorothiazide (HCTZ)	Teva Pharmaceuticals Industries Ltd.

"We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards. This is why we've asked these companies to take immediate action to protect patients," said Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research.

The FDA will continue to investigate this issue and provide additional information when it becomes available. The agency encourages patients and health care professionals to report any adverse reaction to the FDA's MedWatch program.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products

that give off electronic radiation, and for regulating tobacco products.

This announcement was originally published on the Food and Drug Administration website on July 13, 2018.

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