Ongoing Recall of Blood Pressure Drugs

In July 2018, the U.S. Food and Drug Administration (FDA) announced voluntary recalls of certain generic drugs containing the active ingredient valsartan. Since that time, the recall has been expanded to also include some products containing the active ingredients irbesartan or losartan. Drugs in this class of medications are known as angiotensin II receptor blockers or ARBs and have been the subject of ongoing recalls due to the presence of recently discovered impurities.

Presence of Impurities

These blood pressure lowering drugs have been recalled due to the presence of the nitrosamine impurities NDMA (N-Nitrosodimethylamine), NDEA (N-nitrosodiethylamine), or NMBA (N-Nitroso-N-methyl-4-aminobutyric acid). It is important to note, not all drugs containing the active ingredients, valsartan, losartan or irbesartan are affected; only specific manufacturers' products have been recalled. It is thought the impurities may be related to a change in the manufacturing process of the active pharmaceutical ingredient (API). Although NDMA, NDEA, and NMBA are found in some foods, drinking water and air pollution, they are considered unacceptable contaminants in drug products.

These unintended impurities are a concern as they are considered to have the potential to cause cancer. In December 2018, the FDA published acceptable interim levels for nitrosamine impurities in ARBs. Although these impurities should not be detectable in finished drug products, the FDA has set interim limits that will be allowed for these impurities in order to avoid shortages in this class of medications.

Instructions for Patients

Medications in this class of drugs, known as ARBs, are used for treating high blood pressure, heart failure and kidney disease related to diabetes. The contaminated active pharmaceutical ingredients may be found alone or in combination with other blood pressure lowering agents, such as hydrochlorothiazide (HCTZ) or amlopidine.

Patients with impacted product are instructed to continue taking the medication until a replacement product or alternative therapy is available. The risk of harm may be greater if the ARB therapy is discontinued abruptly without an alternative agent being initiated. The FDA estimates that if 8,000 patients consumed the highest daily valsartan dose (320 mg) containing NDMA for four years, one additional case of cancer may occur in those 8,000 individuals.

Additional Information

For additional details, view the FDA's update page. For a complete listing of ARB products that have been recalled, visit the respective FDA webpage: losartan, irbesartan, and valsartan. The

FDA plans to continue to investigate these impurities and provide ongoing communication regarding their findings.

References:

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