

FDA announces voluntary recall of Montelukast tablets by Camber Pharmaceuticals due to incorrect drug in bottles

For Immediate Release

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Release

The U.S. Food and Drug Administration is warning consumers and health care professionals about a voluntary recall of one lot of Montelukast Sodium Tablets – lot number MON17384, expiration 12/31/2019 – by Camber Pharmaceuticals, Inc., Piscataway, N.J. Sealed bottles labeled as montelukast sodium tablets, 10 milligram, 30-count bottle from Camber were found to instead contain 90 tablets of Losartan Potassium Tablets, 50 mg.

This tablet mix-up may pose a safety risk as taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels and low blood pressure. This risk is especially high for pregnant women taking the allergy and asthma medication montelukast because losartan, which is indicated to treat high blood pressure, could harm or kill the fetus. The FDA recommends that consumers who have this recalled product should contact their health care provider or pharmacist immediately.

This recall is not related to the recent valsartan recalls that were due to an impurity, N-nitrosodimethylamine (NDMA).

“We want to ensure that patients who take montelukast are aware of this recall due to the serious risks associated with taking losartan in its place,” said Donald D. Ashley J.D., director of the office of compliance in the FDA’s center for drug evaluation and research. “Patients who take prescription drugs expect and deserve to have the medication their doctor prescribed.”

Montelukast is used to prevent wheezing, difficulty breathing, chest tightness and coughing caused by asthma. It is also used to prevent bronchospasm (breathing difficulties) during exercise and to treat the symptoms of seasonal and perennial allergic rhinitis. Montelukast is in a class of medications called leukotriene receptor antagonists (LTRAs) which work by blocking the action of substances in the body that cause the symptoms of asthma and allergic rhinitis.

Losartan is often used alone or in combination with other medications to treat high blood pressure. Losartan is also used to decrease the risk of stroke in people who have high blood pressure and a heart condition called left ventricular hypertrophy (enlargement of the walls of the left side of the heart).

Patients should contact their health care provider or pharmacist to determine if their medicine has been recalled. Patients should also 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.

Montelukast sodium tablets are beige, rounded square-shaped, film coated tablets that are imprinted with “I” on one side and “114” on the reverse. Losartan tablets are white and oval-shaped with the letter “I” imprinted on one side and the number “5” imprinted on the reverse.

Recalled lots of montelukast sodium tablets, USP 10mg have the following information:

- Label: Montelukast Sodium Tablets 10 mg 30 ct
- Lot number: MON17384
- Expiration date: 12/31/2019
- NDC: 31722-726-30

To date, Camber has not received adverse event reports associated with this recall. The FDA encourages health care professionals and consumers to report adverse events to the FDA’s MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm ([/Safety/MedWatch/default.htm](http://www.fda.gov/medwatch/report.htm)); or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

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.

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