Montelukast – Camber Pharmaceuticals

On August 31, 2018 the U.S. Food and Drug Administration (FDA) announced that Camber Pharmaceuticals Inc. is voluntarily recalling one lot of Montelukast Sodium Tablets – lot number MON17384, expiration 12/31/2019. This product is being recalled because sealed bottles labeled as Montelukast Sodium Tablet, 10 mg, 30-count bottle from Camber were found to instead contain 90 tablets of Losartan Potassium Tablets, 50mg.

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.

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).

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.

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.