Magellan Rx Management
2520 Industrial Row Drive
Troy, MI 48084

September 4, 2018

«PRESCRIBER_FIRST_NAME» «PRESCRIBER_LAST_NAME»
«PRESCRIBER_ADDRESS_LINE_1» «PRESCRIBER_ADDRESS_LINE_2»
«PRESCRIBER_CITY», «PRESCRIBER_STATE_ABBREVIATION» «PRESCRIBER_ZIP_CODE»

RE: FDA Recall Class 1 for Montelukast Sodium Tablets

Dear Dr. «PRESCRIBER_LAST_NAME»,

Magellan Rx Management is the Pharmacy Benefit Management (PBM) Company for Alliant Health Plans. As the PBM, we notify members and prescribers when there has been an FDA Recall or Market Place Withdrawal for medications that are paid for by MagellanRx Management.

The enclosed Memo provides complete details of the current FDA, Class 1 Recall including how you can report adverse events or obtain additional information. This recall is at the Lot level and Magellan Rx Management has identified all paid claims that had the potential to be associated with the Montelukast Sodium Tablet recall. We have also notified your patient(s) who were prescribed this medication and had a paid claim on file with Magellan Rx within the timeframe applicable to the recall.

Sincerely,

MagellanRx Management

Enclosures:
Montelukast Recall Notice

For more information regarding this FDA Recall Notification, please be referred to the FDA website: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM613532.htm?utm_campaign=Untitled%20Email&utm_medium=email&utm_source=Eloqua

FDA contact information for reporting adverse events/quality complaints online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or call the FDA at 1-800-FDA-1088

Montelukast tablets by Camber Pharmaceuticals Recall- due to incorrect drug in bottles

[Posted 08/31/2018]

AUDIENCE: Pharmacy, Patient

ISSUE: The United States (US) Food and Drug Administration (FDA) 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 healthcare 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.”

BACKGROUND: 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 healthcare 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 10 mg have the following information:

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

RECOMMENDATION: To date, Camber has not received adverse event reports associated with this recall. The FDA encourages healthcare 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; 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.

Read the safety alert: FDA Link

Consumers with questions regarding this recall should contact Major Pharmaceuticals Customer Support at 1-800-616-2471, Option #1 available Monday through Friday 8 a.m. – 8 p.m. EST. Consumers can contact their physician or healthcare provider if they have additional questions about this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178.

LINKS:
For additional details regarding this recall, please visit the links provided.

- FDA Press Announcement: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
- Prinston Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613504.htm.
- Teva Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613729.htm.
- Major Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613625.htm.