March 5, 2020 COM-2020-012

DRUG SAFETY NOTIFICATION

DATE: March 4, 2020

DRUG NAME: Montelukast (Singulair)

DRUG INDICATION: Asthma and allergies

SAFETY TOPIC: FDA Strengthens Boxed Warning for Singulair – Restricting Use for Allergic Rhinitis

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on March 4, 2020 the US Food and Drug administration (FDA) published a safety communication for montelukast (Singulair and generics) indicating that they are strengthening existing warnings about serious behavior and mood-related changes with this drug. Montelukast prescribing information already includes warnings about mental health side effects (e.g. suicidal thoughts or actions); however, many healthcare professionals, patients, and/or caregivers are not aware of the risk, and suicides and other side effects continue to be reported. The FDA decided a stronger warning is needed and determined that a Boxed Warning was appropriate.

<u>Recommendations for healthcare professionals:</u>

- Ask patients about any history of psychiatric illness prior to initiating treatment.
- Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine.
- Advise all patients of the risk of neuropsychiatric events when prescribing montelukast.
- Advise patients, parents, and/or caregivers that the patient should stop taking montelukast and contact a health care

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professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.

- Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
- Encourage patients, parents, and/or caregivers to read the Medication Guide they receive with their montelukast prescriptions, which explains the safety risks and provides other important information.
- Report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

Best regards,

PharmPix Clinical Department

Reference(s):

- Singulair (montelukast) and All Generics: Strengthened Boxed Warning. U.S. Food and Drug Administration. (2020). Retrieved March 2020, from https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use.

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