RXADVANCE
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CLINICAL UPDATE

Brand Name	Singulair
Generic Name	montelukast

Clinical Update

FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis.

FDA Approval Date: March 4, 2020

Safety

Montelukast is FDA-approved for asthma and allergies. It is a prescription medicine approved to prevent asthma attacks and for long-term treatment of asthma in adults and children 1 year and older. It is also approved to prevent exercise-induced asthma in patients 6 years and older. In addition, it is approved to help control the nasal symptoms of seasonal outdoor allergies in patients 2 years and older and year-round indoor allergies in those 6 months and older. Montelukast works to help improve symptoms of asthma and allergic rhinitis by blocking substances in the body that may cause them. Montelukast was first approved by FDA in 1998. It is marketed under the brand name Singulair and as generics.

Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine. Counsel all patients receiving montelukast about mental health side effects and advise them to stop the medicine and contact a health care professional immediately if they develop any symptoms. Be aware that some patients have reported neuropsychiatric events after discontinuation of montelukast. Consistent with prior evaluations, a wide variety of mental health side effects have been reported, including completed suicides. Some occurred during montelukast treatment and resolved after stopping the medicine. Other reports indicated that mental health side effects developed or continued after stopping montelukast. The Sentinel study, which studied asthma patients 6 years and older, and other observational studies did not find an increased risk of mental health side effects with montelukast compared to inhaled corticosteroids (ICS). However, the Sentinel study and the observational studies had some limitations which may affect how we interpret the results. Under reviewed animal studies, which showed that montelukast given orally reaches the brain in rats. Although new data regarding the risk of mental health side effects with montelukast are limited, it decided to strengthen the warnings by requiring a Boxed Warning. Due to the wide availability of alternative safe and effective allergy medicines with long histories of safety, we have re-evaluated the risks and benefits of montelukast and have determined it should not be the first choice treatment particularly when allergic rhinitis symptoms are mild.

Patients should stop montelukast and discuss with a health care professional right away if experience behaviour or mood-related changes while taking the medicine. These may include:

- agitation, including aggressive behavior or hostility
- attention problems
- bad or vivid dreams
- depression
- disorientation or confusion
- feeling anxious
- hallucinations (seeing or hearing things that are not really there)
- irritability
- memory problems
- obsessive-compulsive symptoms

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- restlessness
- sleepwalking
- stuttering
- suicidal thoughts and actions
- tremor or shakiness
- trouble sleeping
- uncontrolled muscle movements

Take montelukast for allergic rhinitis or hay fever only if you cannot tolerate other medicines or they do not work for you. Only prescribe montelukast for allergic rhinitis in patients who have an inadequate response or intolerance to alternative therapies

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