

March 31, 2020



Drug Safety Communication: Mental Health Side Effects from Montelukast

Montelukast is a leukotriene receptor antagonist approved for asthma and allergies. On March 4, 2020, the U.S. Food and Drug Administration (FDA) announced it is strengthening existing warnings about serious behavior and mood-related changes with montelukast. While the prescribing information for montelukast already includes warnings about mental health side effects, including suicidal thoughts or actions, many health care professionals are not aware of the risks or alternatives to this medicine.

Mental health side effects associated with use of montelukast 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
- restlessness
- sleepwalking
- stuttering
- suicidal thoughts and actions
- tremor or shakiness
- trouble sleeping
- uncontrolled muscle movements

After conducting an extensive review of available information and convening a panel of outside experts, the FDA is now requiring a *Boxed Warning* be added to the prescribing information. The *Boxed Warning* will describe these serious mental health side effects and recommend that montelukast be reserved to treat allergic rhinitis only in patients who cannot tolerate or are not being treated effectively with other allergy medications.

To minimize risk and benefits of montelukast when deciding whether to prescribe or continue patients on this medicine, health care professionals should consider the following actions:

- Prescribe montelukast for allergic rhinitis only when patients have had an inadequate response or intolerance to alternative therapies.
- Counsel all patients receiving montelukast about the risk of mental health side effects and advise them to stop the medicine and contact a health care professional immediately if they develop any mental health side effects, including suicidal thoughts or actions.
- Be aware that some patients have reported neuropsychiatric events after discontinuation of montelukast.
- Discuss the possible option of other safe and effective allergy medicines with patients and parents or caregivers, including over-the-counter products or allergen immunotherapy..

Previous FDA communications about mental health side effects with montelukast were published in [March 2008](#), [January 2009](#), [June 2009](#), and [August 2009](#).

To read the full safety announcement, which includes a summary of findings from case reports and the results of an observational study conducted using data from the FDA's [Sentinel System](#), refer to the "FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair)" article found on the [Drug Safety and Availability](#) page of the FDA website.