Montelukast (Singulair and generics) is a prescription leukotriene receptor antagonist approved for asthma, exercise-induced bronchoconstriction, and allergic rhinitis. The U.S. Food and Drug Administration (FDA) conducted an observational study using data from the FDA’s Sentinel System and reviewed observational and animal studies in the published literature. As a result, the FDA is strengthening existing warnings to require a Boxed Warning about serious behavior and mood-related changes, including suicidal thoughts or actions, associated with montelukast.

Neuropsychiatric symptoms may include, but is not limited to:

- 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

Most reported cases occurred during montelukast treatment, but some occurred after discontinuation. In many cases, symptoms resolved after discontinuing montelukast, but some patients have reported that symptoms continued after discontinuation.

Prescribers should carefully weigh the risks of neuropsychiatric symptoms versus the potential benefits of montelukast when initiating and continuing prescriptions. Counsel all patients receiving montelukast about potential mental health side effects and advise them to stop the drug and contact a health care professional if they develop any symptoms.

For allergic rhinitis, montelukast should not be the first drug of choice and should be reserved for those who are not treated effectively with or cannot tolerate other allergy medications. Consider antihistamines like loratadine (Alavert, Claritin), fexofenadine (Allegra), cetirizine (Zyrtec), levocetirizine (Xyzal), and diphenhydramine (Benadryl) or intranasal steroid sprays like fluticasone (Flonase), triamcinolone (Nasacort), and budesonide (Rhinocort).

To help the FDA identify and track drug safety issues, health professionals, consumers, and patients can voluntarily report any observed or suspected adverse events to the FDA MedWatch program at https://www.accessdata.fda.gov/scripts/medwatch/.
WARNING: SERIOUS NEUROPSYCHIATRIC EVENTS

Serious neuropsychiatric (NP) events have been reported with the use of SINGULAIR. The types of events reported were highly variable, and included, but were not limited to, agitation, aggression, depression, sleep disturbances, suicidal thoughts and behavior (including suicide). The mechanisms underlying NP events associated with SINGULAIR use are currently not well understood [see Warnings and Precautions (5.1)].

Because of the risk of NP events, the benefits of SINGULAIR may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with alternative therapies. Reserve use of SINGULAIR for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies [see Indications and Usage (1.3)]. In patients with asthma or exercise-induced bronchoconstriction, consider the benefits and risks before prescribing SINGULAIR.

Discuss the benefits and risks of SINGULAIR with patients and caregivers when prescribing SINGULAIR. Advise patients and/or caregivers to be alert for changes in behavior or new NP symptoms when taking SINGULAIR. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, advise patients to discontinue SINGULAIR and contact a healthcare provider immediately [see Warnings and Precautions (5.1)].

Reference: