



Singulair® (montelukast sodium) – New Boxed Warning

- On April 29, 2020, the [FDA approved](#) a new *Boxed Warning* for brand and generic [Singulair \(montelukast\)](#) products regarding the risk of serious neuropsychiatric (NP) events.
- An [FDA Drug Safety Communication](#) regarding the risk of serious mental health effects with montelukast was announced in March 2020.
- Singulair is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients ≥ 12 months of age; prevention of exercise-induced bronchoconstriction in patients ≥ 6 years of age; and for the relief of symptoms of seasonal allergic rhinitis in patients ≥ 2 years of age and perennial allergic rhinitis in patients ≥ 6 months of age.
- Serious NP events have been reported with use of Singulair. These postmarketing reports have been highly variable and included, but were not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor.
- NP events have been reported in patients of all ages with and without a previous history of psychiatric disorder. NP events have been reported mostly during Singulair treatment, but some were reported after Singulair discontinuation.
- 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.
- Singulair should be reserved for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. In patients with asthma or exercise-induced bronchoconstriction, the benefits and risks should be considered before prescribing Singulair.
- Patients and/or caregivers should be advised to be alert for changes in behavior or for new NP symptoms when taking Singulair. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, patients should discontinue Singulair and contact a healthcare provider immediately.
 - In many cases, symptoms resolved after stopping therapy; however, in some cases symptoms persisted after discontinuation.
 - Monitoring and supportive care should continue until symptoms resolve and the benefits and risks of restarting treatment should be re-evaluated if such events occur.



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