

# **FDA: Asthma drug Singulair to get 'black box' warning**

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Asthma and allergy drug montelukast—sold as a generic and under the

brand name Singulair—will get a "boxed warning" over potential ties to neuropsychiatric effects, the U.S. Food and Drug Administration announced Wednesday.

The drug has long carried a warning that it has been linked with an [increased risk](#) for "agitation, depression, sleeping problems, and suicidal thoughts and actions," the FDA said in a statement. The agency's move Wednesday elevates that advisory to its most prominent boxed warning. The new warning advises [health care providers](#) to "avoid prescribing montelukast for patients with mild symptoms, particularly those with allergic rhinitis." Added to the boxed warning, patients who are prescribed montelukast will also get a special Medication Guide outlining potential risks.

The first such warning added to montelukast labeling came in 2008 after reports of suicide and other serious psychiatric events were reported in users. The agency has since tracked and compiled data linking [mental health issues](#) with use of the drug, and a summary was presented at an FDA advisory committee meeting last year. Based on the committee's assessment, "the FDA determined the risks of montelukast may outweigh the benefits in some patients, particularly when the symptoms of the disease are mild and can be adequately treated with [alternative therapies](#)," the agency said.

"We recognize that millions of Americans suffer from asthma or allergies and rely on medication to treat these conditions," Sally Seymour, M.D., who directs the FDA division of pulmonary, allergy, and rheumatology products, said in a statement. "The incidence of neuropsychiatric events associated with montelukast is unknown, but some reports are serious, and many patients and health care professionals are not fully aware of these risks."

**More information:** [More Information](#)

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