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IN BRIEF

Neuropsychiatric Events with Montelukast

The FDA is requiring stronger warnings in the labeling of the leukotriene receptor antagonist montelukast (Singulair, and generics) about the risk of suicidal behavior and other serious neuropsychiatric events associated with its use.1

Montelukast has been FDA-approved for treatment of asthma and allergic rhinitis for many years. Its labeling and the labels of the other leukotriene receptor antagonists, zafirlukast (Accolate, and generics) and zileuton (Zyflo, and generics), which are approved only for treatment of asthma, have included warnings about a risk of neuropsychiatric events since 2009. The FDA now requires a boxed warning in the labeling of montelukast because of continued reports of completed suicides and other behavioral and mood-related adverse events during and after its use.

An FDA review identified 82 cases of completed suicide associated with use of montelukast, many of which were preceded by new-onset neuropsychiatric symptoms. Of the 64 suicides in which the age of the patient was known, 19 occurred in children ≤ 17 years old. Many patients in the 34 better-documented cases had comorbidities or were taking other drugs that are associated with an increased risk of self-harm or behavioral disturbances.1

Multiple large observational studies have found no association between use of montelukast and neuropsychiatric events.2-4 In one case-control study in 4395 children 5-18 years old treated with a maintenance drug for asthma, new-onset psychiatric events occurred almost twice as often in patients who took montelukast as in those treated with other drugs (OR 1.91; 95% CI 1.15-3.18).5

The FDA now recommends that montelukast be used for treatment of allergic rhinitis only when other treatments (such as an intranasal corticosteroid or an oral second-generation antihistamine) have been ineffective or intolerable. Its use for treatment of asthma should be preceded by careful consideration of the drug's risks and benefits.1,6
