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IN THIS ISSUE

In Brief: Neuropsychiatric Events with Montelukastp 65

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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} ■

1. FDA Drug Safety Communications: FDA requires boxed warning about serious mental health side effects for asthma and allergy drug montelukast (*Singulair*); advises restricting use for allergic rhinitis. March 4, 2020. Available at: www.fda.gov/media/135840/download. Accessed April 23, 2020.
2. Sentinel. Neuropsychiatric events following montelukast use: a propensity score matched analysis. September 27, 2019. Available at: <https://bit.ly/2wFz2bs>. Accessed April 23, 2020.
3. MM Ali et al. Exploring the possible association between montelukast and neuropsychiatric events among children with asthma: a matched nested case-control study. *Pharmacoepidemiol Drug Saf* 2015; 24:435.

4. GT Schumock et al. Risk of suicide attempt in asthmatic children and young adults prescribed leukotriene-modifying agents: a nested case-control study. *J Allergy Clin Immunol* 2012; 130:368.
5. SD Glockler-Lauf et al. Montelukast and neuropsychiatric events in children with asthma: a nested case-control study. *J Pediatr* 2019; 209:176.
6. Drugs for allergic disorders. *Med Lett Drugs Ther* 2017; 59:71.

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