RXADVANCE
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Montelukast (Singulair® and generics) Safety Alert

Date of Notice: 03/04/2020

Brief Description of Safety Alert

On March 4, 2020, the FDA has issued a black box warning about behavior and mood-related changes with the use of montelukast (Singulair® and generics). Prescribing information for montelukast already includes warning about mental health side effects, including suicidal thought or actions.

Because of the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines. For allergic rhinitis, also known as hay fever, the FDA has determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy drugs. For patients with asthma, the FDA recommends that health care professionals consider the benefits and risks of mental health side effects before prescribing montelukast.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
montelukast oral packet, 4mg	All NDCs	All lots	All dates
montelukast tablets, 10mg	All NDCs	All lots	All dates
montelukast chewable tablets, 4mg & 5mg	All NDCs	All lots	All dates
Singulair® oral packet, 4mg	0006-3841-30	All lots	All dates
Singulair® tablets, 10mg	0006-9117-31 0006-9117-54	All lots	All dates
Singulair® chewable tablets, 4mg & 5mg	0006-1711-31 0006-9275-31	All lots	All dates

Prescriber Information

Prescribers should consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the drug. Counsel all patients receiving montelukast about mental health side effects and advise them to stop the drug and contact a doctor immediately if they develop behavior or mood-related symptoms. Be aware that some patients have reported neuropsychiatric events after discontinuation of montelukast.

Only prescribe montelukast for allergic rhinitis in patients who have an inadequate response or intolerance to alternative therapies.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Patients, parents, or caregivers should stop montelukast and discuss with a doctor right away if you or your child experiences behavior or mood-related changes while taking this drug.

RxAdvance Response

RxAdvance encourages members to contact their prescriber or pharmacist if you have questions about the use of montelukast.