

“Early Communication” from FDA re: Singulair

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The FDA has released an “Early Communication” about an ongoing safety review of Singulair (montelukast), a medicine in a class of drugs known as leukotriene receptor antagonists and commonly used in the treatment of asthma and allergies. It is important to keep in mind that the FDA release of this information does not mean that FDA has concluded there is a causal relationship between the drug and the possible safety concern. Nor does it mean that FDA is advising health care professionals to discontinue or to stop prescribing the drug. Rather, the FDA will be reviewing the safety concern and make a determination as to whether further action is warranted. The FDA will be providing updates as more information becomes available, but this will likely take several months.

Specifically, the FDA is investigating a *possible association* between the use of Singulair and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide. There have been post-marketing reports of central nervous system effects including tremor, depression, suicidality (suicidal thinking and behavior), and anxiousness that have caused the maker of Singulair, Merck & Co, Inc., to update the prescribing information and patient information for Singulair over the past year.

Other leukotriene modifying medications include Accolate (zafirlukast) and Zyflo (zileuton). The FDA is reviewing post-marketing reports it has received of the same possible behavioral/mood effects with these drugs as well.

Patients should NOT STOP taking Singulair before talking to their doctor if they have questions or concerns about this new information. *If patients do have any concern about the safety of these medications for themselves or their family members, or a change in behavior or mood has been noted, please make an appointment to discuss these concerns with your doctor as soon as possible.* Your doctor will review your asthma control, your need for and response to these drugs, and appropriate alternatives for therapy available.

This is the Joint statement on FDA investigation of Singulair from the national professional organizations in allergy and asthma, the AAAAI and ACAAI:

MILWAUKEE - Leadership from the American Academy of Allergy Asthma & Immunology and the American College of Allergy, Asthma & Immunology today released the following statement in response to the Thursday announcement of a Food and Drug Administration investigation into Singulair:

There are no data from well-designed studies to indicate a link between Singulair and suicide. The concern expressed by the FDA is based entirely on case reports and there is no indication that such effects apply to other leukotriene-modifying medications.

Post-marketing case reports are incomplete. Furthermore, comparative data are lacking on the incidence of suicide in the general population versus the incidence in patients taking Singulair. Thus, it is unknown whether there is an increased incidence of suicide in patients receiving Singulair.

Based on the information currently available, patients taking Singulair should continue to take the medication as prescribed provided: 1) the patient and physician feel the medication is effective; and 2) the patient does not experience any suicidal behavior or thoughts.

Patients who experience suicidal thoughts or demonstrate suicidal behavior should consult their physician immediately to discuss whether to continue with this medication. Patients should not hesitate to consult their physician if they feel uncomfortable continuing on the medication.