

Trinity Allergy, Asthma and Immunology Care, P.C.

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Dear Patient/ Parent:

You or your child may be taking Singulair tablets or Granules for the treatment of asthma and or allergic rhinitis. There is a recent concern about a possible link between using Singulair and tremor, depression, suicidality (suicidal thinking and behavior), and anxiousness. The FDA is currently investigating this matter and according to the FDA, it may take up to 9 months before it can pass an opinion on this matter. Until then I recommend that we follow the following guidelines from the American Academy of Allergy Asthma & Immunology and the American College of Allergy, Asthma & Immunology.

Joint statement on FDA investigation of Singulair from 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.

Following is the text from FDA web site.

“FDA is investigating a possible association between the use of Singulair and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide. Singulair is a medicine in the drug class known as leukotriene receptor antagonists. Singulair is used to treat asthma and the symptoms of allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose) and to prevent exercise-induced asthma.

Over the past year, the maker of Singulair, Merck & Co, Inc., has updated the prescribing information and patient information for Singulair to include the following post-marketing adverse events: tremor (March 2007), depression (April 2007), suicidality (suicidal thinking and behavior) (October 2007), and anxiousness (February 2008).

In February 2008, FDA and Merck discussed how best to communicate these labeling changes to prescribers and patients. Merck plans to highlight the recent changes in the prescribing information in face-to-face interactions with prescribers and provide prescribers with patient information leaflets about Singulair. The Singulair website includes the most current prescribing information and patient information for Singulair (www.singulair.com).

FDA is working with Merck to further evaluate a possible link between the use of Singulair and behavior/mood changes, suicidality and suicide in response to inquiries received by FDA. FDA has requested that Merck evaluate Singulair study data for more information about suicidality and suicide. FDA is reviewing the postmarketing reports it has received of behavior/mood changes, suicidality and suicide in patients who took Singulair.

Due to the complexity of the analyses, FDA anticipates that it may take up to 9 months to complete the ongoing evaluations. As soon as this review is complete, FDA will communicate the conclusions and recommendations to the public.

Singulair is an effective medicine that is indicated for the treatment of asthma and symptoms of allergic rhinitis. Patients should not stop taking Singulair before talking to their doctor if they have questions about this new information. Until further information is available, healthcare professionals and caregivers should monitor patients taking Singulair for suicidality (suicidal thinking and behavior) and changes in behavior and mood.

Other leukotriene modifying medications include zafirlukast (Accolate), which is also a leukotriene receptor antagonist and zileuton (Zyflo and Zyflo CR), which is a leukotriene synthesis inhibitor. FDA is reviewing postmarketing reports it has received of behavior/mood changes, suicidality and suicide in patients who took Accolate, Zyflo, and Zyflo CR and will assess whether further investigation is warranted.

This early communication is in keeping with FDA’s commitment to inform the public about its ongoing safety reviews of drugs.

The FDA urges both healthcare professionals and patients to report side effects from the use of Singulair, Accolate, Zyflo, and Zyflo CR to the FDA's MedWatch Adverse Event Reporting program

- on-line at [www.fda.gov/medwatch/report.htm];
- by returning the postage-paid FDA form 3500 [available in PDF format at www.fda.gov/medwatch/getforms.htm] to 5600 Fishers Lane, Rockville, MD 20852-9787;

- faxing the form to 1-800-FDA-0178; or
- by phone at 1-800-332-1088 “

Please contact us if you have any questions or need further clarifications.

Yours truly,

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