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

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<Mail Merge Patient Name & Address Here>

Dear patient:

The U.S. Food and Drug Administration have provided further updated safety information on leukotriene modifiers. The FDA has requested that manufacturers include a precaution in the drug prescribing information (drug labeling) regarding neuropsychiatric events (behavior, mood changes) that have been reported in some persons taking Montelukast (Singulair), Zafirlukast (Accolate), and Zileouton (Zyflo and Zyflo CR).

The reported neuropsychiatric events include post-market cases of agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking and behavior (including suicide), and tremor.

If you (or your family member) are taking any one of the above medications, are concerned about the potential for neuropsychiatric events with these medications, then you should make an appointment with us and talk to us about alternative treatment choices. Please be aware that stopping these medications without discussing with your doctor or us could potentially result in worsening of asthma and allergy symptoms. If you have any questions, please call us at 928-681-5800.

Yours truly,

Natarajan Asokan, M.D.

Drugs

Updated Information on Leukotriene Inhibitors: Montelukast (marketed as Singulair), Zafirlukast (marketed as Accolate), and Zileuton (marketed as Zyflo and Zyflo CR)

6/12/2009

Updated information

Neuropsychiatric events have been reported in some patients taking montelukast (Singulair), zafirlukast (Accolate), and zileuton (Zyflo and Zyflo CR). FDA has requested that manufacturers include a precaution in the drug prescribing information (drug labeling).

Montelukast 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. Zafirlukast and zileuton are used to treat asthma.

The reported neuropsychiatric events include postmarket cases of agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking and behavior (including suicide), and tremor.

This information reflects FDA's current analysis of available data concerning this drug.

To report any serious adverse events associated with the use of this drug, please contact the FDA MedWatch program using the contact information at the bottom of this web page.

Advice to patients and healthcare professionals

- Patients and healthcare professionals should be aware of the potential for neuropsychiatric events with these medications.
- Patients should talk with their healthcare providers if these events occur.
- Healthcare professionals should consider discontinuing these medications if patients develop neuropsychiatric symptoms.

Background

In April 2009, FDA completed its review of neuropsychiatric events, (mood and

behavioral changes) possibly related to drugs that act through the leukotriene pathway (montelukast, zafirlukast, zileuton). As part of its review, FDA reviewed post-marketing reports and also requested that manufacturers submit all available clinical trial data for these products.

The post-market reports of patients on these medications included cases of neuropsychiatric events. Some reports included clinical details consistent with a drug-induced effect. In the clinical trial data submitted by manufacturers, neuropsychiatric events were not commonly observed. However, the available data were limited because the trials were not designed to look for neuropsychiatric events. Sleep disorders (primarily insomnia) were reported more frequently with all three products compared to placebo.

Previous Early Communications

- Early Communication About an Ongoing Safety Review of Montelukast (Singulair)
- Follow-up to the March 27, 2008, Communication about the Ongoing Safety Review of Montelukast (Singulair)

Contact Us

- 1-800-FDA-0178 Fax
- **MedWatch Online**

Regular Mail: Use postage-paid FDA Form 3500

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