

FDA looks into Singulair®, risks of suicidal thoughts

By Elizabeth Weise, USA TODAY

The Food and Drug Administration is investigating anecdotal reports that people who use Singulair, the popular asthma and allergy drug, are at greater risk for suicidal thoughts and suicide.

Singulair is a pill prescribed to treat asthma and hay fever symptoms such as sneezing and a nose that is stuffy, runny or itchy. It blocks an inflammation pathway in the body that can cause both asthma and allergy symptoms.

It was approved for treating asthma in 1998 and to treat seasonal allergy symptoms in 2003.

In the past year, drugmaker Merck of Whitehouse Station, N.J., has added tremors, depression, suicidal thinking and behavior, and anxiety to the list of possible adverse side effects it gives doctors about the drug.

Singulair had sales of \$4.3 billion last year and has been used by "millions," says Merck's George Philip, who directs Singulair product development.

The FDA has asked Merck to look at Singulair study data for more information about reports of behavior and mood changes, suicidal thoughts and suicide in patients who took the drug. Because such reviews are very complex, the FDA says it may take nine months to complete its evaluation.

In the meantime, the agency is asking doctors and health care providers to carefully monitor their patients taking Singulair.

The FDA is not recommending that patients stop taking the drug, suggesting instead that they talk to their doctor if they have concerns.

Reports of possible links to suicidal thoughts have come to Merck "anecdotally from physicians, from patients and from parents or relatives," Philip says. But because the information the company receives can be "quite sketchy," Philip says it's not possible to definitively link the drug and these reported episodes.

The government agrees with that assessment. The FDA went public with its concerns about this drug as part of its ongoing safety reviews. But in a release, the agency said this "does not mean that FDA has concluded there is a causal relationship between the drug product and the emerging safety issue."

The FDA "is considering, but has not reached a conclusion" about whether it needs to further regulate the drug and will update the public as more information becomes available.

Singulair belongs to a class of drugs called leukotriene receptor antagonists. The FDA reports that it will investigate whether similar medications, such as Accolate, Zflo and Zflo CR, have negative effects on behavior and mood.