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## **FDA adds a box warning for montelukast (Singulair® and generics) regarding the risk of mental health side effects (which may include suicidal thoughts or actions).**

Montelukast (Singulair®) is a leukotriene inhibitor used to treat asthma and allergies.

The FDA is strengthening the mental health side effect warnings (including suicidal thoughts and actions) to be more prominently displayed as a boxed warning. Other common side effects of montelukast include upper respiratory infection, fever, headache, sore throat, cough, stomach pain, diarrhea, earache or ear infection, flu, runny nose, and sinus infection.

For **patients with allergic rhinitis**, the FDA recommends that montelukast only be used in patients who have an inadequate response or intolerance to alternative therapies.

For **patients with asthma**, the FDA recommends that health care professionals consider the benefits and risks of mental health side effects before prescribing montelukast.

### **Health care professionals should:**

- Ask patients about any history of psychiatric illness prior to initiating treatment.
- Advise all patients of the risk of neuropsychiatric events when prescribing montelukast.
- Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.
  - Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
  - Most reported cases of neuropsychiatric events occurred during montelukast treatment, but some occurred after discontinuation.
- Provide the new Medication Guide which explains the safety risks and provides other important information and encourage patients to read it.

The complete montelukast Drug Safety Communication can be [viewed on the FDA website](#).

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To help the FDA track safety issues with medicines, please report adverse events involving montelukast or other medicines to the FDA MedWatch program as recommended in the [Indian Health Manual](#). Instructions for reporting can be found online at the [NPTC Pharmacovigilance website](#).