

What is the Black Box Warning for montelukast?

The FDA announced a Black Box Warning, in early 2020, for montelukast (generic for Singulair) regarding neuropsychiatric events that may develop. This medication has been available since 1998 and our physicians have been using it for the treatment of asthma, exercise induced bronchospasm and allergic rhinitis since its development. In general we've seen excellent results in the majority of cases.

Montelukast has been associated with some side effects. Although we have seen them in some patients, they are not common. In general our vast experience has been that side effects start within the first week of treatment and are temporary until the medication is stopped. It would be very unusual for someone to develop side effects if it has been tolerated, already, for months or years.

Side effects include:

In younger children: a range of abdominal pain, nightmares and night terrors, fussy or angry behavior, to new bed-wetting.

In preteens, teens and young adults: more likely to be mood-changing behavior, as in sadness and depression. There have been very rare cases of suicidal thoughts and suicide. These symptoms can develop, independently of medications, in this age group.

We counsel our patients to monitor for any side effects within the first two weeks of treatment. At the time of prescribing, if there is a concern about a family history of mental health illness, the risks, benefits and alternatives are considered. Stopping the medication usually resolves all associated symptoms within a few days. The use of montelukast has not been linked to creating a chronic behavior/mental health disease for patients.

Is there a substitute for montelukast?

Montelukast is approved for the treatment of asthma, exercise induced bronchospasm and allergic rhinitis. There might be appropriate alternative medications, including inhaled/nasal steroids, biologic injection medications and allergen immunotherapy (allergy shots). Alternatives treatments should be discussed with your doctor to customize it to your needs.

There is one another medication in the same pharmaceutical class as montelukast, known as Accolate or zafirlukast. This has been available longer than montelukast has. It is generally more expensive than montelukast. It may have a similar neuropsychiatric side effect profile but less is known about this medication since it is not as widely used. It comes in adult and pediatric doses, but all are tablets to be swallowed, not chewable, and is taken twice daily.

If you still have concerns or questions about using montelukast, please call our office and make an appointment to meet with the prescribing doctor.