

Singulair's Mental Health Risks Are Now Laid Bare

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STORY AT-A-GLANCE

- › Singulair, an asthma medication, has been linked to mental health issues such as depression, anxiety and aggression due to its significant binding to brain receptors. Since 1998, there have been 82 suicides associated with its use, prompting the FDA to add a black box warning in 2020
- › Despite the serious mental health risks, the FDA has not updated Singulair's label to reflect these dangers, leading to criticism from the incumbent New York Attorney General, calling out the agency for more decisive action to protect the public
- › The current manufacturer of Singulair maintains that it is safe, despite the mounting evidence and reports of adverse psychiatric effects from patients and health care professionals
- › A study on Montelukast's impact on brain activity found no significant cognitive improvements but did observe changes in EEG patterns, indicating neurophysiological effects that require further research, especially in elderly patients
- › Managing asthma naturally is a safer approach, and it is done by addressing the root cause of autoimmune disease. Strategies such as optimizing vitamin D levels, using healthy fats for cooking and supporting lung function with natural remedies like butterbur are recommended

Asthma is a chronic respiratory disease characterized by airway inflammation and constriction, affecting millions globally. Many of those who have this chronic condition are prescribed a drug called Singulair, generically known as montelukast. This drug

reduces symptoms by targeting leukotriene receptors that contribute to inflammation, offering an alternative for patients who do not respond adequately to inhaled corticosteroids.

But as with most medications, taking Singular/montelukast has side effects. Concerning research is emerging regarding its effects on mental health, raising concern among health care providers, government agencies and patients alike.

Evidence Highlights Mental Health Risks of Taking Singular/Montelukast

A report published in The Defender exposed the alarming mental health risks associated with Singular. The investigation aimed to determine the magnitude of Singular's effects on mental function. The motive was spurred by growing concerns from patients and health care professionals about the drug's severe side effects.¹

How does Singular cause these side effects? In a bombshell report by the U.S. Food and Drug Administration (FDA), their researchers discovered that Singular attaches to multiple brain receptors critical to psychiatric functioning. Once the drug enters your system, it disrupts normal brain processes, leading to mental dysfunction.²

The findings support numerous reports from patients who have experienced depression, suicidal thoughts, anxiety and aggression while taking this drug. In fact, the FDA had already counted 82 suicides related to Singular and its generic versions since 1998.³

Julia Marschallinger, Ph.D., a biologist who studied Singular, emphasized that based on the data, "It's definitely doing something that's concerning." Marschallinger's research aligns with the FDA's findings, providing a scientific basis for the observed mental health issues.⁴

Jessica Oliphant, Ph.D., deputy director at the FDA's National Center for Toxicological Research, further stated, "These data indicate that montelukast is highest in brain

regions known to be involved in psychiatric effects," highlighting the drug's direct impact on areas of the brain responsible for mental health.⁵

The article also noted that prior research already showed Singulair penetrates the brains of animal test subjects, reinforcing the FDA researchers' findings.⁶ However, it remains unclear whether this binding mechanism directly causes harmful effects in individual patients or identifies which patients have the highest risk. Despite this uncertainty, the correlation between Singulair usage and adverse psychiatric events is undeniable.

Authorities Have Already Given Montelukast a Black Box Warning

In 2020, recognizing the gravity of the situation, the FDA added a black box warning to Singulair and generic montelukast labels. This warning serves as the strictest caution for certain medications, alerting potential users to the "serious potential side effects" associated with the drug. The timing of this warning coincides with the FDA's internal research to delve deeper into why Singulair triggers such severe neuropsychiatric side effects.⁷

Merck, the original manufacturer of Singular/montelukast, is already facing multiple lawsuits alleging that the company already knew about the drug's effects on brain function.⁸ These lawsuits claim that Merck minimized the drug's psychiatric side effects in communications materials with drug regulators to prioritize profits over patient safety. Today, Singulair is manufactured by Merck's spin-off company, Organon.⁹

Letitia James, the incumbent Attorney General for the State of New York, has also taken a stand, urging the FDA to act to "prevent further unnecessary health risk" posed by Singulair.¹⁰ In a letter dated February 21, 2024, James emphasized that it has been nearly four years since the FDA strengthened existing warnings about Singulair's mental and behavioral health side effects.

Furthermore, the Attorney General outlined several actions the FDA could take to better safeguard children from Singulair's side effects.¹¹ These recommendations include

enhancing monitoring systems for adverse drug reactions and ensuring that health care providers are fully informed about the risks associated with Singulair.

Montelukast Alters Brain Activity Without Cognitive Gains

Another study, published in *Brain Sciences*, investigated how montelukast affects brain activity and cognitive functions in humans. The researchers selected 12 asthma patients aged between 38 and 73 years who were prescribed montelukast as their sole asthma therapy. Electroencephalogram (EEG) recordings and administering neuropsychological tests were conducted over an eight-week period.

The researchers found that while montelukast did not lead to significant improvements in memory, attention or mood based on neuropsychological scales, it induced notable changes in EEG patterns. Specifically, participants exhibited decreased entropy during rest and episodic memory tasks, along with alterations in brain rhythms.

These findings indicate that montelukast influences brain activity, even though these changes did not translate into measurable cognitive changes within the study's timeframe.¹²

Delving deeper, the EEG results revealed a decrease in entropy at follow-up during rest, revealing a reduction in the complexity of brain wave patterns. During episodic memory acquisition, there was a further decrease in entropy and an acceleration of the background rhythm. These changes reflect how montelukast affects the brain's electrical activity, altering how neurons communicate during cognitive tasks.¹³

Additionally, during tasks requiring visual attention, the researchers observed an increase in gamma power alongside a slowing of the background rhythm. For context, gamma power is associated with high-level cognitive functions like attention and memory processing, while changes in background rhythms influence overall brain responsiveness.

Going back to the study, these alterations in brain wave activity show that montelukast has a tangible impact on neural processes that eventually leads to worsening brain

health, as shown in the report by The Defender.¹⁴

However, the study's small sample size of 12 participants significantly constraints the findings, which the researchers also acknowledged. With a small group and a short treatment duration of eight weeks, it is challenging to draw definitive conclusions about montelukast's effects on cognitive functions across a broader population. The absence of baseline cognitive impairments in participants further complicates the ability to detect meaningful changes.¹⁵

Despite these limitations, the observed neurophysiological changes open new avenues for understanding how montelukast interacts with the central nervous system. The decrease in entropy and alterations in brain rhythms indicate that montelukast modulates neural activity in ways not yet fully understood.

For example, the modulation is linked to montelukast's mechanism of action, which involves blocking leukotriene receptors that play a role in inflammation and immune responses within the brain.¹⁶

Leukotrienes are chemicals in the body that contribute to inflammation and are involved in the body's response to allergens and infections. By blocking these receptors, Montelukast reduces inflammation in the lungs, allowing asthmatic patients to breathe easier.

However, leukotriene receptors are also present in the brain, where they influence processes related to inflammation and neural function. The study suggests that by blocking these receptors, Montelukast alters brain activity, as evidenced by the changes in EEG patterns.¹⁷

Digging Deeper Into Montelukast's Effects on Brain Function

The findings raise important questions about the broader neurological implications of chronic montelukast use. While the study did not find direct cognitive benefits, the changes in brain activity will have other effects that were not measured within the scope set by the researchers.

For instance, altered brain rhythms and decreased entropy will eventually influence how the brain responds to stress or recovers from injury, and these areas are ripe for further investigation in future studies.¹⁸

For example, examining elderly patients or those with preexisting cognitive impairments will be able to provide insights into the risk montelukast poses in these populations. As noted by the researchers, conducting a double-blind study with longer-term treatment phases will help eliminate biases and provide more robust data on the cognitive and neurological effects.¹⁹ In fact, another study has already led the way.

In a meta-analysis that reviewed 59 studies published in the European Respiratory Review, montelukast shows no significant association with suicide or depression, but there are notable links to anxiety and sleeping disorders. Specifically, montelukast users exhibited a 1.21 times higher risk of developing anxiety-related conditions and a 1.13 hazard ratio for sleep disturbances within a year of use.²⁰

Natural Strategies for Supporting Asthma

At its core, asthma is an autoimmune disease. Therefore, treatment is ideally focused on addressing the root cause of autoimmune disease, which is usually a nutrient deficiency or an inflammatory diet. To support healthy immune function and optimal cellular energy production, here are my recommendations:

- 1. Optimize your vitamin D levels** – I recommend having your blood tested to know where your current vitamin D levels. For optimal health, try to get a range between 60 and 80 ng/mL. To achieve this, getting regular sunlight exposure is important, but there are caveats.

For example, a diet high in linoleic acid (LA) will cause DNA damage when sunlight hits your skin because of oxidation. To understand the intricacies of optimizing your vitamin D levels, I recommend you read my article "[Vitamin D Deficiency Complicates Autoimmune Diseases.](#)"

There, I discuss the role of vitamin D in enhancing both innate and adaptive immunity to suppress inflammatory responses, as well as tips to protect your skin from harm when taking in sunlight.

2. Replace vegetable oils – Eliminate all vegetable oils from your diet. These fats accumulate in brain tissue and disrupt normal neurotransmitter function. Instead, cook nutritious, homemade meals with healthy fats like grass fed butter, tallow and ghee.

Beware that many foods sold today also contain LA, so be sure to track your intake with an app like Cronometer. Ideally, your LA intake should be below 5 grams per day.

3. Support lung function naturally – Butterbur reduces bronchial inflammation and helps prevent asthma attacks. Additionally, an active ingredient from coralberry leaves called FR900359 blocks bronchial muscle contraction more effectively than common asthma medications.

4. Avoid asthma triggers – Many people find significant improvement by eliminating lectins, which trigger inflammation throughout the body including the airways and brain. Focus on low-lectin foods like leafy greens and root vegetables while avoiding high-lectin foods like grains, legumes and nightshade vegetables.

In addition, making changes to your environment will help reduce the chances of triggering asthma. Make a list of possible allergens that trigger your asthma, such as dust, stress, infection and the presence of mold in your home. Then, plan out how to reduce your exposure to these allergens.²¹

Sources and References

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