



# New Boxed Warning for montelukast (Singulair): Due to Serious Mental Health Side Effects

## What has changed?

The FDA recently announced in a Drug Safety Communication that montelukast (Singulair) would receive a new boxed warning to emphasize the existing warnings related to serious mental health side effects.

## Why is there a new boxed warning?

The decision to strengthen the existing warnings to a Boxed Warning was considered due to lack of awareness by patients, caregivers and health care providers. The FDA continues to receive reports of mental health side effects including completed suicides. Given the many available options to treat allergic rhinitis the use of montelukast (Singulair) should also no longer be considered first line and risk versus benefit should be assessed for use in asthma.

## How will this affect your prescribing?

- **For allergic rhinitis**
  - Reserve therapy for when a patient is not treated effectively with or cannot tolerate other allergy medications
  - Consider alternative allergy medications as first line including oral second-generation antihistamines (cetirizine, loratadine), antihistamine nasal spray (azelastine) or steroid nasal spray (fluticasone propionate)
- **For asthma**
  - Health care professionals should consider risk vs benefit before prescribing or continuing medication

## What should healthcare professionals do if considering use of montelukast (Singulair)?

- Ask all patients about any psychiatric history prior to initiating treatment
- Counsel all patients about mental health side effects and advise them to stop immediately and contact a health care professional if they develop
- Monitor all patients for neuropsychiatric symptoms as these may occur even in those without a prior history
- Continue monitoring patients even after discontinuation, while most events occur while on the medication there is potential to experience after discontinuation
- Advise your patients to review the medication guide to understand the signs/symptoms of mental health side effects
- Submit an FDA MedWatch form to report adverse events related to montelukast use
  - <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

## References

1. FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis. Retrieved March 27, 2020 from <https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use>