

[Montelukast \(Singulair\): reminder of the risk of neuropsychiatric reactions](#)

Prescribing tip for information

Montelukast sodium is an oral leukotriene receptor antagonist. It is indicated for patients 6 months and older:

- for the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom “as-needed” short acting beta-agonists provide inadequate clinical control of asthma.
- in those asthmatic patients in whom montelukast is indicated, montelukast can also provide symptomatic relief of seasonal allergic rhinitis.
- for the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.

A recent [MHRA alert](#) was issued as a reminder to prescribers that neuropsychiatric reactions may occur in association with montelukast treatment, and these reactions are listed as possible side effects in the product information. A [recent EU review](#) confirmed the known risks of neuropsychiatric reactions and found that the magnitude of risk was unchanged. However, the review identified some cases in which there had been a delay in neuropsychiatric reactions being recognised as a possible adverse drug reaction.

Prescribers should be alert for neuropsychiatric reactions in patients taking montelukast and carefully consider the benefits and risks of continuing treatment if they occur.

Advice for healthcare professionals:

- be alert for neuropsychiatric reactions in patients taking montelukast; events have been reported in adults, adolescents, and children (see list of reported events below)
- advise patients and their caregivers to read carefully the list of neuropsychiatric reactions in the patient information leaflet and seek medical advice immediately should they occur
- evaluate carefully the risks and benefits of continuing treatment if neuropsychiatric reactions occur
- be aware of newly recognised neuropsychiatric reactions of speech impairment (stuttering) and obsessive–compulsive symptoms
- report suspected adverse drug reactions associated with montelukast to the [Yellow Card Scheme](#)

In the UK, the most frequently reported suspected neuropsychiatric reactions associated with montelukast have been nightmares/night terrors, depression, insomnia, aggression, anxiety and abnormal behaviour or changes in behaviour. These events were reported in all age groups. However, nightmare/night terrors, aggression, and behaviour changes are more frequently reported in the paediatric population.

To contact the Medicines Optimisation Team please phone 01772 214302