**Montelukast: reminder of the risk of neuropsychiatric reactions**

Healthcare professionals prescribing montelukast should be alert to the risk of neuropsychiatric reactions in **all** patients including children and adolescents. Reported neuropsychiatric reactions include **sleep disorders, hallucinations, anxiety, and depression**, as well as **changes in behaviour and mood**.

**Healthcare professionals should advise patients and their caregivers to be alert to these risks and seek medical advice as soon as possible if neuropsychiatric reactions occur.**

**Advice for healthcare professionals:**

* the warnings in the Patient Information Leaflet and Summary of Product Characteristics for all montelukast products in the UK have been strengthened and highlighted with a black box for greater emphasis.
* be alert for neuropsychiatric reactions in patients taking montelukast; events have been reported in adults, adolescents, and children.
* discontinue montelukast if patients experience new or worsening symptoms of neuropsychiatric reactions.
* advise patients and their caregivers to carefully read the list of neuropsychiatric reactions in the Patient Information Leaflet and to seek medical advice immediately should they occur.
* report **all** suspected adverse drug reactions associated with montelukast using the Yellow Card scheme. Access to the yellow card scheme can be found using this link to the [**Yellow Card scheme**](https://yellowcard.mhra.gov.uk/)**.**

**Advice for healthcare professionals to give to patients and caregivers**

* infrequently, some patients may experience new or worsening changes in mood, sleep or behaviour such as nightmares, aggression, anxiety or thoughts about self-injury while using montelukast. You should seek immediate medical attention if you or your child experiences these symptoms; your prescriber is best placed to advise you on stopping this medicine if needed.
* it is very important to tell your friends and family that you are taking montelukast and that this medicine is associated with infrequent neuropsychiatric side effects. You may not notice some changes in your mood, sleep, and behaviour. Other people may notice changes or new symptoms that you need to talk to your prescriber about.
* the Patient Information Leaflet that comes with all montelukast products now includes warnings and advice about these psychiatric side effects in a black box. It is important to read the Patient Information Leaflet that comes with your medicine or your child’s medicine
* patients, parents, and caregivers can report suspected adverse drug reactions to montelukast via the yellow card scheme. Access can be found using this link to the [**Yellow Card scheme**](https://yellowcard.mhra.gov.uk/)**.**

Since first authorised in the UK in 1998, there have been approximately 44 million prescriptions of montelukast issued. During this time, the MHRA has received 1,223 reports of suspected neuropsychiatric adverse reactions.

When reporting it is important that you provide as much information as possible, including information about batch numbers, medical history, any concomitant medication, onset timing, treatment dates, and product brand name.