

## **Montelukast: New boxed warning to raise further awareness of the risk of neuropsychiatric events**

Montelukast is an orally active leukotriene receptor antagonist indicated for use in the prophylaxis and treatment of asthmatic conditions.\*

The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC), having completed a review of data related to the known risk of neuropsychiatric events with montelukast, has recommended a new boxed warning in product information\*\* to further raise awareness of this risk.

Neuropsychiatric events such as behavioural changes, depression and suicidality have been reported in all age groups taking montelukast. The symptoms may be serious and can continue if treatment is not withdrawn.

Healthcare professionals are advised that treatment with montelukast should be discontinued if neuropsychiatric symptoms occur during treatment.

Patients and/or caregivers should be advised to be alert for symptoms and to notify their physician if changes in behaviour occur.

A new boxed warning will be included in both the Summary of Product Characteristics (SmPC) and the package leaflet to raise further awareness.

### **Key Messages to Healthcare Professionals**

- Neuropsychiatric events such as behavioural changes, depression and suicidality have been reported in all age groups taking montelukast.
- The symptoms of neuropsychiatric events may be serious and can continue if treatment with montelukast is not withdrawn.
- If neuropsychiatric symptoms occur, treatment with montelukast should be discontinued.
- Product information (Summary of Product Characteristic and Patient Leaflet) is being updated with a new boxed warning to further raise awareness of this risk.

\* Products currently authorised that contain montelukast, include, Montelair, Montelukast, and Singulair. Further details are available at [www.hpra.ie](http://www.hpra.ie).

\*\* The approved product information is made up of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) and is available at [www.hpra.ie](http://www.hpra.ie).