



## Direct Healthcare Professional Communication

Feb 2025

### **Montelukast: Reminder of serious neuropsychiatric events associated with Montelukast**

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to Remind you **about serious neuropsychiatric events associated with Montelukast.**

#### ***Summary***

- EDA received a serious case of suicidal behavior in patient aged 4 years old taking montelukast.
- Neuropsychiatric effects may occur in all age groups taking montelukast, these effects include behavioural changes, depression and suicidal thoughts.
- Healthcare professionals(HCPs) are reminded about the potential neuropsychiatric effects associated with montelukast.
- HCPs should be vigilant for neuropsychiatric reactions in patients taking montelukast and carefully evaluate the risks and benefits of continuing treatment with montelukast if such events occur.
- EDA recommends that HCPs should educate patients and their carers to be alert for changes in behaviour or for new neuropsychiatric symptoms and to seek medical advice immediately, this is especially important if the patient is a child.
- Safety information has been added to montelukast product information to strengthen and highlight warnings about serious neuropsychiatric events.

#### ***Background on the safety concern***

Montelukast is a medicine used to prevent and treat chronic asthma in adults and children and for symptomatic seasonal allergic rhinitis (hay fever).

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Montelukast is an orally active compound which has been shown in asthmatic patients to reduce peripheral blood eosinophil counts and sputum eosinophils, which are parameters of asthmatic inflammation.

A range of neuropsychiatric reactions association with montelukast include:

- sleep disturbances, depression and agitation including aggressive behaviour
- disturbances of attention or memory
- hallucinations and suicidal thinking

### **References:**

**TGA:** <https://www.tga.gov.au/news/safety-updates/more-prominent-safety-warnings-about-neuropsychiatric-effects-montelukast>

### **Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://vigiflow-eforms.who-umc.org/eg/med>

QR Code:

PO Box: 11451

Hotline: 15301

