Saudi Food & Drug Authority (SFDA)

SAFETY COMMUNICATION

10 October 2019

Montelukast: reminder of the risk of neuropsychiatric reactions

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about the occurrence of neuropsychiatric reactions in patients using montelukast.

- Be alert for neuropsychiatric reactions in patients using montelukast; events have been reported in adults, adolescents, and children
- 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

Neuropsychiatric reactions may occur in association with montelukast treatment, and these reactions are listed as possible side effects in the product information. A recent 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. Therefore, we remind healthcare professionals about the possible risks with montelukast and the need to consider the benefits and risks of continuing treatment if they occur.

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Singulair improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms.

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.

The following table demonstrates all registered trade names for Montelukast in Saudi Arabia:

SINGULAIR	BRONCHOFAST	ANTIKAST	ZECAST	LEUKAIR
AIRFAST	BRONCAST	MONCAS	YOCAIR	LUKRA
MONTEL	BREMAX	LUXAT	MONTAS	
ACTAMONE	ALLAIR	RELUKAST	EMCAST	

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges healthcare professionals to report ADEs to the SFDA using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 Northern ring branch re-
Hitteen District
Riyadh 13513 - 7148
Kingdom of Saudi Arabia
Reporting hotline: 19999
Fax: +966112057662
Email: npc.drug@sfda.gov.sa
Webpage: http://ade.sfda.gov.sa