



## SAFETY ALERT

DRAP SAFETY ALERT NO. 11

### SERIOUS MENTAL HEALTH SIDE EFFECTS WITH ASTHMA AND ALLERGIC DRUGS MONTELUKAST. FDA REQUIRES BOX WARNING AND ADVISED RESTRICTION IN USE FOR ALLERGIC RHINITIS.

**Date:** 6<sup>th</sup> April, 2020

#### Target Audience:

- Healthcare Professionals.
- Patients, consumers or caregivers.

#### Problem or Issue:

United States Food and Drug Administration (FDA) on 4<sup>th</sup> March, 2020 vide a Drug Safety Communication informed that they are strengthening existing warnings about the serious behavior and mood related changes with montelukast (Singulair and generics) after a review of available information led them to reevaluate the benefit and risks of montelukast use. The prescribing information of montelukast already includes warnings about mental health side effects, including suicidal thoughts or actions. But, FDA panel of experts recommended Boxed Warning to convey stronger warning to patient and healthcare professional. Due to risk of mental health side effects, the benefit of montelukast may not outweigh the risks in some patients, particularly when symptoms of disease may be mild and adequately treated with other medicines. Therefore, FDA determined that for allergic rhinitis (hay fever), the montelukast should be reserved for those who are not treated effectively with allergic medicines; and for patient with asthma, FDA recommended that healthcare professionals consider the benefit and risks of mental health side effects before prescribing montelukast.

#### Therapeutic Goods Affected:

Name: **Montelukast (Singulair and all its generics)**

Montelukast is an US-FDA approved prescription only drug for prevention and long-term treatment of asthma in adults and children 1 year and older. It is also used to prevent exercise-induced asthma in patients of 6 years and older. In addition, is also used to help control the nasal symptoms of seasonal outdoor allergies in patient 2 years and older and year-round indoor allergies patient of 6 months and older. Montelukast works to help improve symptoms of asthma and allergic rhinitis by blocking substance in the body that may cause them.

#### Advice for Healthcare Professionals:-

1. Health care professionals should consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine.
2. Only prescribe montelukast for allergic rhinitis in patients who have an inadequate response or intolerance to alternative therapies.
3. Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine.
4. Advise all patients of the risk of neuropsychiatric events when prescribing montelukast.





5. Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.
6. Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
7. Report neuropsychiatric or any other suspected adverse drug reaction to Pakistan National Pharmacovigilance Centre, DRAP.

#### Advice for Patients/ Caregivers and Relatives:-

1. Serious mental health side effects have occurred in patients with and without a history of mental illness.
2. Stop taking montelukast and notify a health care professional right away if you or your child experience behavior or mood-related changes while taking the medicine. These may include:

<ul style="list-style-type: none"><li>• <i>agitation, including aggressive behavior or hostility</i></li><li>• <i>attention problems</i></li><li>• <i>bad or vivid dreams</i></li><li>• <i>depression</i></li><li>• <i>disorientation or confusion</i></li><li>• <i>feeling anxious</i></li><li>• <i>hallucinations (seeing or hearing things that are not really there)</i></li><li>• <i>irritability</i></li></ul>	<ul style="list-style-type: none"><li>• <i>memory problems</i></li><li>• <i>obsessive-compulsive symptoms</i></li><li>• <i>restlessness</i></li><li>• <i>sleepwalking</i></li><li>• <i>stuttering</i></li><li>• <i>suicidal thoughts and actions</i></li><li>• <i>tremor or shakiness</i></li><li>• <i>trouble sleeping</i></li><li>• <i>uncontrolled muscle movements</i></li></ul>
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3. Talk to your health care professional about any history of mental illness before starting treatment.
4. You should take montelukast for allergic rhinitis or hay fever only if you cannot tolerate other medicines or they do not work for you. Many other safe and effective allergy medicines are widely available, talk to your healthcare professionals in case you intend to change montelukast for allergic rhinitis.

Both healthcare professionals and patients are requested to report serious behavior and mood-related changes or any other suspected adverse drug reactions to **Pakistan National Pharmacovigilance Centre**, Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance e-reporting system** [http://:https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK](http://https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK) or at [npc@dra.gov.pk](mailto:npc@dra.gov.pk).

