Montelukast to Get Boxed Warning 3/6/2020

The FDA is requiring a boxed warning for the asthma and allergy drug montelukast (Singulair) due to concerns over the risk for neuropsychiatric events. The boxed warning applies to the brand name versions and all generics.

The addition of the boxed warning strengthens existing language in montelukast's prescribing information about mental health side effects, including suicidal ideation and behavior. Adverse events have been reported in patients with and without pre-existing psychiatric disease.

For allergic rhinitis, the FDA says montelukast should be prescribed only if other medications have failed or patients can't tolerate them.

The agency advises clinicians to inform patients about montelukast's risks before prescribing it and to monitor patients for neuropsychiatric symptoms during treatment.

Before stopping, please contact our office for change of treatment plan.