

## Safety Alert

Aug 2024

**Quetiapine – Concomitant administration of quetiapine and other serotonergic medications, such as MAO inhibitors, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, or tricyclic antidepressants, may cause serotonin syndrome, a potentially fatal condition**

**EDA performs label update to include the following:**

### **Special warnings and precautions for use**

#### **Serotonin syndrome**

Concomitant administration of Quetiapine and other serotonergic medications, such as MAO inhibitors, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants may **cause serotonin syndrome**, a life-threatening condition.

If concomitant treatment with other serotonergics is clinically justified, careful observation of the patient is advised, especially during treatment initiation and dose increases. **Symptoms of serotonin syndrome** may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.

If serotonin syndrome is suspected, a dose reduction or discontinuation of treatment should be considered based on the severity of symptoms.

#### **Interaction with other medicinal products and other forms of interaction**

Quetiapine should be used with caution in combination with serotonergic medications, such as MAO inhibitors, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants, as **which increases the risk of serotonin syndrome**, a life-threatening condition

#### **Background:**

##### **Quetiapine is indicated for:**

- Schizophrenia treatment
- Bipolar disorder treatment:
  - For the treatment of moderate to severe manic episodes in bipolar disorder
  - For the treatment of major depressive episodes in bipolar disorder
  - For the prevention of recurrence of manic or depressive episodes in patients with bipolar disorder who have previously responded to treatment with quetiapine.
- The additional treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have not had an optimal response to treatment with antidepressant monotherapy.

#### **References:**

*AEMPES* ([Click here](#))