

## Safety Alert

March 2025

### Esketamine nasal spray – Risks of Bradycardia and Seizure

EDA performs label update to include the following:

#### Undesirable effects:

##### **Cardiac Disorders:**

Uncommon: Bradycardia

##### **Nervous System Disorders:**

Rare: Seizure

#### **Background:**

#### Therapeutic Indication

Esketamine is indicated for :

- Adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.
- Co-administered with oral antidepressant therapy, is indicated in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency.

#### References:

EMA ([Click here](#))