

## Safety Alert

July 2024

### Pseudoephedrine – new contraindications and risk of PRES and RCVS

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

#### **Contraindications**

- Severe hypertension or uncontrolled hypertension
- Severe acute or chronic kidney disease/renal failure

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

**Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)**

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure.

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

#### **4.8 Undesirable effects**

Posterior reversible encephalopathy syndrome (PRES)  
Reversible cerebral vasoconstriction syndrome (RCVS)”

#### **Background:**

#### **Therapeutic Indication**

Pseudoephedrine is indicated in adults and adolescents 12 years and older for the symptomatic treatment of seasonal allergic rhinitis when accompanied by nasal congestion.

#### **References:**

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