

## Safety Alert

Sep. 2025

### Hydrocortisone (Systemic formulation) – Risk of Thyrotoxic Periodic Paralysis (TPP)

EDA performs label update to include the following:

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

Thyrotoxic Periodic Paralysis (TPP) can occur in patients with hyperthyroidism and with hydrocortisone-induced hypokalaemia. TPP must be suspected in patients treated with hydrocortisone presenting signs or symptoms of muscle weakness, especially in patients with hyperthyroidism.

If TPP is suspected, levels of blood potassium must be immediately monitored and adequately managed to ensure the restoration of normal levels of blood potassium.

#### **N.B :**

#### **This Safety Alert will be applied to all systemic formulation of Hydrocortisone except:**

- Products indicated in adrenal insufficiency in a modified release tablet formulation
- Products indicated for adrenal insufficiency, paediatric use only

#### **Background:**

#### **Thyrotoxic Periodic Paralysis (TPP)**

Thyrotoxic Periodic Paralysis (TPP) is a condition causing sudden, severe muscle weakness, particularly in the limbs, due to a sudden drop in blood potassium levels (hypokalemia). It is triggered by a state of hyperthyroidism (excess thyroid hormone) and is often seen in young Asian males, though it can affect others. Attacks are brought on by high-carbohydrate meals, exercise, or stress. Treatment involves correcting the low potassium, potentially with potassium supplements, and managing the underlying hyperthyroidism to prevent future episodes.

#### **Therapeutic Indication**

Anti-inflammatory agent. Hydrocortisone is indicated for any condition in which rapid and intense corticosteroid effect is required such as:

- Collagen diseases
- Dermatological diseases
- Allergic states
- Gastro-intestinal diseases
- respiratory diseases
- Medical emergencies

#### **Reference**

EMA ([click Here](#))