

Safety Alert

Oct. 2025

Roxadustat- Thrombocytopenia & increased blood copper levels

EDA performs label update to include the following:

Undesirable effects

Blood and lymphatic system disorders: Thrombocytopenia (common)

Investigations: blood copper increased (Not known)

Background:

Thrombocytopenia

Thrombocytopenia is the medical term for a condition characterized by an abnormally **low level of platelets** (also known as thrombocytes) in the blood.

People with mild thrombocytopenia often have no symptoms. If the count is very low, symptoms may include:

- Easy or excessive bruising.
- Tiny, pinpoint red or purple spots on the skin (petechiae), often on the lower legs.
- Prolonged bleeding from minor cuts.
- Bleeding from the gums or nose.
- Blood in the urine or stool.
- Unusually heavy menstrual periods.

Blood copper increased

Increased blood copper levels, medically known as hypercupremia, indicate that the amount of copper circulating in the blood is higher than the normal range. While copper is an essential trace mineral, excessive amounts can be toxic and lead to serious health issues.

Therapeutic Indication

It is a medicine that increases the number of red blood cells and hemoglobin level in your blood

Reference

EMA ([click Here](#))