

Safety Alert

April. 2026

vancomycin – risk of hemolytic anemia and Hepatobiliary disorders

EDA performs label update to include the following:

Special warning and precautions

Cardiovascular and cerebrovascular effects

Cases of Kounis syndrome have been reported in patients treated with vancomycin. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction .

Undesirable effects

Blood and lymphatic system disorder:

Not known haemolytic anemia

Cardiac disorders

Not known: Kounis syndrome

Hepatobiliary disorders:

Common: alanine aminotransferase increased, aspartate aminotransferase increased.

Background:

Hemolytic anemia is a disorder where red blood cells are destroyed faster than the body can replace them.

Key Characteristics

When red blood cells break down rapidly, they release a byproduct called bilirubin, leading to:

- Jaundice: Yellowing of the skin and eyes.
- Dark Urine: A "tea-colored" appearance.
- Anemia Symptoms: Extreme fatigue, paleness, and shortness of breath due to low oxygen levels.

Hepatobiliary disorders refer to any condition affecting the liver (the body's filter) or the biliary system (the gallbladder and ducts that transport bile).

Biomarkers: High levels of ALT and AST in a blood test serve as a signal that the liver is currently experiencing some form of irritation or injury.

Key Characteristics

- Jaundice: Yellowing of the skin/eyes.
- Abdominal Pain: Usually in the upper right side.
- Metabolic Changes: Fatigue or nausea as the body struggles to process waste.

Therapeutic Indication :

• **For intravenous use :**

- in all age groups by infusion for the treatment of the following serious infections:
- infections of the skin and tissues below the skin
- infections of bone and joints

- infection of the lungs called "pneumonia"
- infection of the inside lining of the heart (endocarditis) and to prevent endocarditis in patients at risk when undergoing major surgical procedures
- Meningitis
- infection in the blood linked to the infections listed above.
- **For intraperitoneal use:**
- for the treatment of peritoneal dialysis infections.
- **For oral use :**
- Treatment of small bowel and colon mucosal infections (pseudo-membranous colitis)

Reference

EMA ([click Here](#))

