

Safety Alert

Mar 2023

A new warning about Vancomycin and Risk of risk of Kounis syndrome

EDA performs label update to include the following:

CLINICAL PARTICULARS

Adverse effects (undesirable effects)

Immune system disorders

Anaphylaxis and hypersensitivity reactions with chills, nausea, urticaria, macular rash, fever and rigors. Kounis syndrome has also been reported.

Background on the safety concerns

”Kounis syndrome Mechanism ”

The mechanism of Kounis syndrome (KS) involves release of inflammatory cytokines through mast cell activation, which leads to coronary artery vasospasm and/or atheromatous plaque erosion or rupture . KS has been described with multiple conditions, including a variety of environmental exposures and drugs .

Symptoms of Kounis syndrome

Cardiac symptoms, including chest pain, coronary vasospasm, angina pectoris, myocardial infarction, acute cardiac failure, and sudden cardiac death associated with subclinical, clinical, acute, or chronic allergic reactions constitute the clinical manifestations of Kounis syndrome.

References:

TGA ([Click here](#))