

Safety Alert

March 2025

Lidocaine– New warning about risk of Kounis Syndrome

EDA performs label update to include the following:

Special warnings and precautions for use

Cardiovascular

Kounis syndrome:

There have been reports of lidocaine-induced hypersensitivity reactions leading to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction). Kounis syndrome can develop in patients with and without cardiac risk factors, and may present with cardiac and/or allergic symptoms.

Sensitivity/Resistance

There have been reports of lidocaine-induced hypersensitivity reactions leading to Kounis syndrome

Undesirable effects:

Cardiovascular System:

Kounis syndrome:

There have been reports of lidocaine-induced hypersensitivity reactions leading to Kounis syndrome

Background:

Kounis syndrom

Kounis syndrome (KS) has been defined as cardiovascular symptoms that occur secondary to allergic or hypersensitivity insults. It was thought to be a rare condition but is now being more commonly identified as the cause of acute coronary events in patients without previous history of coronary artery disease (CAD). The most identified KS cases have been provoked by medications on elderly male patients.

References:

Health Canada ([Click here](#))