

Safety Alert

July 2024

Ibuprofen – Risk of Kounis Syndrome

EDA performs label update to include the following:

Special warnings and precautions for use

Cardiovascular and cerebrovascular effects

Cases of **Kounis syndrome** have been reported in patients treated with ibuprofen-containing products .

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

Cardiac Disorders with a frequency
not known : **Kounis syndrome**

Background:

- Kounis syndrome is a ubiquitous disease which represents a magnificent natural paradigm and nature's own experiment in a final trigger pathway implicated in cases of coronary artery spasm and plaque rupture. Kounis syndrome seems to be not a rare disease but an infrequently diagnosed clinical entity which has revealed that the same mediators released from the same inflammatory cells are also present and in acute coronary events of non allergic etiology. These cells are not only present in the culprit region before plaque erosion or rupture but they release their contents just before an actual coronary event.
- Also known as “allergic angina”, “allergic myocardial infarction”, or “coronary hypersensitivity disorder”, the vasospastic changes seen in Kounis syndrome do not always lead to infarction
- Induced by various conditions, drugs, environmental exposures, foods and coronary stents.

References:

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