

## Safety Alert

Oct 2023

### Ibuprofen/Paracetamol - risks of Kounis syndrome & fixed drug eruption

EDA performs label update to include the following:

#### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hypersensitivity reactions to Mersynofen can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to Mersynofen.

#### Fixed Drug Eruption

Cases of Fixed Drug Eruption (FDE) have been reported with ibuprofen. Ibuprofen should not be reintroduced in patients with history of ibuprofen-related FDE.

#### 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

##### **Skin and subcutaneous tissue disorders:**

Unknown: Drug Reaction with Eosinophilia with Systemic Symptoms (DRESS), Fixed Drug Eruptions (FDE).

##### **Cardiac disorders:**

Unknown: Kounis syndrome.

#### **Background:**

**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).

**A fixed-drug eruption (FDE)** is an immunological cutaneous adverse reaction characterized by sharply defined lichenoid lesion/s which occur/s at the same location every time there is exposure to the causative substance .

#### **References:**

Medsafe ([Click here](#))