

Consumer Update

Feb 2023

Clopidogrel—risk of hemorrhage with aspirin

EDA performs Label Update to include the following:

Warnings

Blood and lymphatic system disorders

very rare: Serious cases of bleeding, mainly skin, musculo-skeletal (haemarthrosis, haematoma), eye (conjunctival, ocular, retinal) and respiratory tract bleeding (haemoptysis, pulmonary haemorrhage), epistaxis, haematuria and haemorrhage of operative wound. Fatal haemorrhage, especially intracranial, gastrointestinal and retroperitoneal haemorrhage.

Cases of serious haemorrhage have been reported in patients taking clopidogrel concomitantly with aspirin or clopidogrel with aspirin and heparin

Background:

CONTRAINDICATIONS

Due to the presence of both components of the product, -Clopidogrel/ Aspirin 75/100 is contraindicated in case of:

Hypersensitivity to clopidogrel, salicylates or any of the excipients.

Severe liver impairment.

Active pathological bleeding such as haemophilia, intracranial haemorrhage or gastrointestinal bleeding.

Peptic ulcer or erosive gastritis

Breast-feeding

In addition, due to the presence of aspirin, its use is also contraindicated in case of:

Hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and in patients

with the syndrome of asthma with rhinitis and/or nasal polyps. Patients with pre-existing mastocytosis, in whom the use of acetylsalicylic acid may induce severe hypersensitivity reactions (including circulatory shock with flushing, hypotension, tachycardia and vomiting).

Severe renal impairment.

References: TGA ([Click here](#))