

# Carceva 75

Clopidogrel 75 mg Tablet

## COMPOSITION

Each film coated tablet contains Clopidogrel Hydrogen Sulfate BP equivalent to Clopidogrel 75 mg.

## PHARMACOLOGY

Clopidogrel is a prodrug. It inhibits platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y<sub>12</sub> class of ADP receptors on platelets. Dose-dependent inhibition of platelet aggregation can be seen 2 hours after single oral doses. Repeated doses of 75 mg per day inhibit ADP-induced platelet aggregation on the first day, and inhibition reaches steady state between Day 3 and Day 7.

## INDICATION

### Acute Coronary Syndrome (ACS):

It is indicated to reduce the rate of myocardial infarction (MI) and stroke in patients with non-ST-segment elevation ACS [unstable angina (UA)/non-ST-elevation myocardial infarction (NSTEMI)].

It is indicated to reduce the rate of myocardial infarction and stroke in patients with acute ST-elevation myocardial infarction (STEMI).

### Recent MI, recent Stroke, or established Peripheral Arterial Disease:

In patients with established peripheral arterial disease or with a history of recent myocardial infarction (MI) or recent stroke it is indicated to reduce the rate of MI and stroke.

## DOSAGE AND ADMINISTRATION

### Acute Coronary Syndrome:

In patients who need an antiplatelet effect within hours, initiate clopidogrel with a single 300 mg (4 tablets) oral loading dose and then continue at 75 mg once daily. Initiating it without a loading dose will delay establishment of an antiplatelet effect by several days.

### Recent MI, Recent Stroke, or Established Peripheral Arterial Disease:

75 mg once daily orally without a loading dose.

It is given orally with or without food.

## CONTRAINDICATION

Clopidogrel is contraindicated in the following conditions:

- Hypersensitivity to the drug substance or any component of the product.
- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

## WARNING AND PRECAUTION

- As it is a prodrug, so metabolism to its active metabolite is impaired by genetic variations in CYP2C19 (poor metabolizer) and by the drugs that inhibit CYP2C19 such as Omeprazole and Esomeprazole. Concomitant use with these drugs and in CYP2C19 poor metaboliser may reduce the antiplatelet activity of Clopidogrel.
- As it inhibits platelet aggregation for the lifetime of the platelet (7-10 days), risk of bleeding may increase. To restore hemostasis, platelet transfusions within 4 hours of the loading dose or 2 hours of the maintenance dose may be less effective.
- Discontinuation of Clopidogrel increases the risk of cardiovascular events. Discontinue 5 days prior to elective surgery that has a major risk of bleeding. Resume Clopidogrel as soon as hemostasis is achieved.
- Thrombotic Thrombocytopenic Purpura (TTP) has been reported that requires urgent treatment including plasmapheresis (plasma exchange).
- Hypersensitivity including rash, angioedema or hematologic reaction has been reported in patients receiving clopidogrel or history of hypersensitivity to other thienopyridines.

## SIDE EFFECT

Clopidogrel is generally well tolerated drug.

Common side effects: Bleeding, Diarrhoea, gastrointestinal discomfort, haemorrhage, Skin reactions.

Rare side effects: Acquired haemophilia, anaemia, angioedema, arthralgia, arthritis, bone marrow disorders.

## USE IN PREGNANCY & LACTATION

There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if clearly needed. It is unknown whether clopidogrel is excreted in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## USE IN SPECIFIC POPULATION

Safety and effectiveness in pediatric populations have not been established. No dosage adjustment is necessary in elderly patients.

## DRUG INTERACTION

- NSAIDs, warfarin, selective serotonin and serotonin norepinephrine reuptake inhibitors (SSRIs, SNRIs): Increases risk of bleeding
- CYP2C19 inhibitors (omeprazole or esomeprazole): Avoid concomitant use of omeprazole or esomeprazole
- Repaglinide (CYP2C8 substrates): Avoid concomitant use of Clopidogrel with Repaglinide as it increases plasma concentrations of Repaglinide

## OVER DOSAGE

Overdose following clopidogrel administration may lead to bleeding complications. Based on biological plausibility, platelet transfusion may restore clotting ability.

## STORAGE CONDITION

Keep below 30°C temperature in a dry place. Protected from light. Do not freeze. Keep out of the reach of children.

## HOW SUPPLIED

Each box contains 30 tablets in alu-alu blister pack.