

Carceva *Plus*

Clopidogrel 75 mg & Aspirin BP 75 mg Tablet

COMPOSITION

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

PHARMACOLOGY

Carceva plus is a fixed dose combination containing Clopidogrel & Aspirin. Clopidogrel is a prodrug. It inhibits platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y₁₂ class of ADP receptors on platelets. Dose-dependent inhibition of platelet aggregation can be seen at 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. Aspirin inhibits platelet aggregation by irreversible inhibition of platelet cyclooxygenase and thus inhibiting the generation of thromboxane A₂ a powerful inducer of platelet aggregation and vasoconstriction.

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)] and acute ST-segment elevation ACS [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

The recommended oral dose is one tablet daily.

CONTRAINDICATION

This combination 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

- This combination may prolongs the bleeding time.
- Thrombotic thrombocytopenic purpura (TTP): TTP has been reported rarely following use of this combination.
- Reye's syndrome: Reye's syndrome may develop in individuals who have chicken pox, influenza or flu symptoms. Hypersensitivity including rash, angioedema or hematologic reaction has been reported in patients receiving this combination or history of hypersensitivity to other thienopyridines

SIDE EFFECTS

This combination is generally well tolerated.

USE IN PREGNANCY & LACTATION

There are no adequate and well-controlled studies in pregnant women. It should be used during first and second trimesters of pregnancy only if clearly needed. It is contraindicated during the third trimester of pregnancy. It is unknown whether Clopidogrel is excreted in human breast milk but Aspirin is known to be excreted in human milk. This Drug should be discontinued during the breast feeding.

DRUG INTERACTION

Oral anticoagulants, NSAIDs, Metamizole, SSRIs, CYP2C19 inhibitors increase the risk of bleeding. It shows interaction with Tonofovir, Valproic acid, Varicella vaccine, Acetazolamide and Nicorandil.

OVER DOSAGE

Clopidogrel overdose may lead to bleeding complications. Based on biological plausibility, platelet transfusion may restore clotting ability. In moderate aspirin intoxication dizziness, headache, tinnitus, confusion, and gastrointestinal symptoms may occur which can be treated by inducing vomiting followed by gastric lavage if needed. In severe Aspirin intoxication respiratory alkalosis respiratory acidosis, metabolic acidosis, hyperthermia, perspiration, dehydration can occur. It can be treated with haemodialysis and other symptomatic treatment.

STORAGE

Keep in a cool & dry place (below 30°C), protected from light & moisture. Keep out of the reach of children.

PACKING

Each box contains 30's tablets in Alu-Alu blister within Alu-Alu Sachet Pack.



Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.

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