

Aspirel

Clopidogrel & Aspirin

Composition Aspirel Tablet: Each film-coated tablet contains Clopidogrel 75 mg as Clopidogrel Bisulphate USP and Aspirin BP 75 mg.

Description: It is a fixed dose combination containing Clopidogrel and Aspirin. Clopidogrel is an inhibitor of platelet aggregation. Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP Mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Aspirin is also an antiplatelet agent. It acts by causing irreversible inhibition of the cyclo-oxygenase enzyme.

Indications: Prevention of atherosclerotic events in patients with history of symptomatic atherosclerotic diseases (ischemic stroke, myocardial infarction or acute coronary syndrome).

Dosage and Administration: The recommended dose is one tablet once daily.

Side Effects: The drug is generally well tolerated. Side effects that have been reported include abdominal pain, dyspepsia, gastritis, diarrhea, nausea, vomiting, constipation, gastrointestinal hemorrhage, ulceration, neutropenia, rash, palpitation, syncope, drowsiness, asthenia, neuralgia, paresthesia and vertigo.

Contraindication: Hypersensitivity to Clopidogrel Hypersensitivity to Aspirin and/or nonsteroidal anti-inflammatory agents Recent history of gastrointestinal bleeding. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage, or bleeding disorders like hemophilia.

Drug Interactions: The safety of chronic concomitant administration of Aspirin, Heparin, Nonsteroidal Anti-inflammatory Drugs (NSAIDs), Warfarin, Phenytoin, Tamoxifen, Tolbutamide, Warfarin, Torsemide, Fluvastatin with Clopidogrel has not been established. However, concomitant use should be undertaken with caution.

Precautions: General: As with other anti-platelet agents, this combination drug should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an anti-platelet effect is not desired, Clopidogrel and Aspirin should be discontinued 7 days prior to surgery. **GI Bleeding:** The combination of Clopidogrel and Aspirin prolongs the bleeding time. So, it should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). **Thrombotic thrombocytopenic purpura (TTP):** TTP has been reported rarely following use of Clopidogrel. **Nasal polyps or nasal allergies:** The combination drug of Clopidogrel and Aspirin should be administered with caution in patients with nasal polyps or nasal allergies.

Hepatic or Renal Impairment: This should be avoided in patients with impaired hepatic and renal function. Aspirin causes sodium and water retention in patients with renal impairment and increases the risk of gastrointestinal bleeding.

Pregnancy & Lactation: Pregnancy: Adverse effects are increased in the mother and the fetus following chronic ingestion of Aspirin. Because of possible adverse effects on the neonate and the potential for increased maternal blood loss, Clopidogrel and Aspirin should be avoided during the last three months of pregnancy.

Lactation: Clopidogrel and Aspirin should be avoided in nursing mothers because of the possible risk of developing Reye's syndrome. Regular use of high doses of Aspirin could impair platelet function and produce hypoprothrombinemia in infants if neonatal vitamin K levels are low.

Pediatric Use: Safety and effectiveness of Clopidogrel and Aspirin in the pediatric population has not been established.

Storage Condition: Store in a cool and dry place. Protect from light and moisture.

Presentation: Aspirel Tablet: Each box contains 3x10's Tablet in Alu-Alu blister pack.