

W=100 mm

Ecosprin[®] Plus

Tablets

Clopidogrel 75 mg + Aspirin 75 mg

COMPOSITION

Each film coated tablet contains Clopidogrel Bisulphate USP equivalent to Clopidogrel 75 mg and Aspirin BP 75 mg.

PHARMACOLOGY

Ecosprin[®] Plus is a fixed-dose combination containing Clopidogrel and Aspirin. Clopidogrel is a thienopyridine derivative that selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP-mediated activation of the GP IIb/IIIa complex, thereby inhibiting platelet aggregation.

Aspirin is an antiplatelet agent. It is an acetylsalicylic acid. Aspirin acts by causing irreversible inhibition of the cyclo-oxygenase enzyme, which leads to decreased formation of Thromboxane A₂. Since platelets do not synthesize new enzyme, the action of Aspirin on platelet cyclo-oxygenase is permanent, lasting for the life of the platelets (7-10 days).

INDICATIONS

Ecosprin[®] Plus is indicated for the prevention of ischemic events, myocardial infarction, stroke and cardiovascular death in patients with acute coronary syndrome.

DOSAGE AND ADMINISTRATION

Route of administration : Oral

The recommended dose is one tablet of Ecosprin[®] Plus daily.

OR AS DIRECTED BY THE PHYSICIANS.

CONTRAINDICATIONS

- Hypersensitivity to Clopidogrel and Aspirin.
- Recent history of gastrointestinal bleeding.
- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage or bleeding disorders like hemophilia.
- Patients with chicken pox, influenza or flu symptoms.

WARNING & PRECAUTIONS

It should not be given to children, particularly those under 12 years. Aspirin may be a contributory factor in the causation of Reye's syndrome in some children. Salicylates should be used with caution in patients with a history of peptic ulceration or hemophilia and other bleeding disorders. These may also induce gastrointestinal hemorrhage. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, Clopidogrel should be discontinued 7 days prior to surgery. It prolongs the bleeding time. So it should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions (particularly gastrointestinal and intraocular). Patients should be informed that it may take them longer time than usual to stop bleeding when they take this drug and they should report any unusual bleeding to the physicians. This drug should be used with caution in hepatically and renally impaired patients.

SIDE EFFECTS

The combination of Clopidogrel and Aspirin 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, drowsiness, asthenia, neuralgia, paraesthesia and vertigo.

USE IN PREGNANCY AND LACTATION

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

Nursing Mother : As Aspirin is excreted in breast milk, this drug should be avoided in nursing mothers because of the possible risk of developing Reye's syndrome.

DRUG INTERACTIONS

Salicylates may enhance the effect of anticoagulants, oral hypoglycemic agents, phenytoin and sodium valporate. Non-steroidal Anti-inflammatory Drugs (NSAIDs): Concomitant administration of Clopidogrel with Naproxen is associated with gastrointestinal blood loss. Warfarin: The safety of the co-administration of Clopidogrel with Warfarin has not been established. Concomitant administration of these two agents should be taken with caution.

STORAGE

Store below 30° C temperature & dry place, protected from light.
Keep all medicines out of reach of children.

PACKING

Each box contains 4 x 10 tablets in blister.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness

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