

Noclog[®]

Clopidogrel Film Coated Tablet

DESCRIPTION

Noclog[®] is a preparation of Clopidogrel Bisulfate, an inhibitor of platelet aggregation. By inhibiting platelet functions it decreases morbid events in people with established cardiovascular atherosclerotic diseases as evidenced by stroke or transient ischemic attacks, myocardial infarction, unstable angina or the need for vascular bypass or angioplasty.

INDICATIONS

Noclog[®] is indicated for the patients with a history of recent myocardial infarction (MI) and stroke, or established peripheral arterial diseases. It is also indicated for patients with acute coronary syndrome e.g. unstable angina/non-Q-wave MI, including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention.

DOSAGE AND ADMINISTRATION

Recommended dose for the patients with recent MI and recent stroke, or established peripheral arterial diseases is 75 mg once daily. For patients with acute coronary syndrome (unstable angina/non-Q-wave MI), it should be initiated with a single 300-mg loading dose and then continued at 75 mg once daily.

CONTRAINDICATION

Noclog[®] is contraindicated in patients with known hypersensitivity to Clopidogrel Bisulfate or any component of the product and in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

SIDE-EFFECTS

The clinically important adverse events observed GI hemorrhage, intracranial hemorrhage, neutropenia or agranulocytosis, abdominal pain, dyspepsia, gastritis, constipation, syncope, palpitation, neuralgia, paraesthesia, vertigo, skin rash etc.

PRECAUTIONS

Clopidogrel prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions. It should be used with caution in patients who have lesions with a propensity to bleed.

USE IN PREGNANCY AND LACTATION

Pregnant women: There are no adequate and well-controlled studies in pregnant women. However, pregnant women should take clopidogrel only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from it, 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.

DRUG INTERACTIONS

Aspirin: Concomitant administration of 500 mg of aspirin twice a day for 1 day did not significantly increase the prolongation of bleeding time induced by clopidogrel. Clopidogrel potentiates the effect of aspirin on collagen-induced platelet aggregation.

Heparin: Clopidogrel did not necessitate modification of the heparin dose or alter the effect of heparin on coagulation. Co-administration of heparin had no effect on inhibition of platelet aggregation induced by clopidogrel.

NSAIDs: Concomitant administration of clopidogrel and NSAIDs were associated with increased occult gastrointestinal blood loss. NSAIDs and clopidogrel should be co-administered with caution.

Warfarin: Because of the increased risk of bleeding, the concomitant administration of warfarin with clopidogrel should be undertaken with caution.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Noclog[®] FCT : Box containing 2/3/4 strips of 10 tablets each. Each film coated tablet contains Clopidogrel Bisulfate USP equivalent to Clopidogrel 75 mg.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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