

Loplate[®] Tablet

Clpidogrel USP 75 mg

COMPOSITION

Each film coated tablet contains Clopidogrel Bisulfate USP equivalent to Clopidogrel 75 mg.

DESCRIPTION

Clopidogrel is a selective ADP receptor antagonist to inhibit platelet aggregation. Clopidogrel selectively inhibits the binding of Adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP-mediated activation of the glycoprotein IIb/IIIa complex, thereby inhibiting platelet aggregation.

INDICATION

Loplate is indicated for the prevention of atherosclerotic events in patients with history of symptomatic atherosclerotic disease (ischemic stroke, myocardial infarction or established peripheral arterial disease). It is also given prophylactically as an alternative to aspirin in patients at risk of thrombo-embolic disorders such as myocardial infarction and stroke.

DOSAGE & ADMINISTRATION

The recommended dose of Loplate is 75 mg once daily, with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease.

SIDE EFFECTS

Clopidogrel is generally a well tolerated drug. A few common side-effects like hemorrhage (including gastro-intestinal and intracranial), abdominal discomfort, nausea, vomiting, diarrhoea, headache, dizziness, vertigo, paraesthesia, rash, pruritus, hepatic and biliary disorder & neutropenia may occur. There have been reports of hepatitis, cholestatic jaundice or hyperlipidemia may occur during long-term therapy.

CONTRAINDICATION

Patients who are hypersensitive to Clopidogrel shouldn't use Loplate. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

DRUG INTERACTION

Drugs that may cause bleeding in ulcerative cases like aspirin or NSAIDs should be used with caution to patients taking Clopidogrel. No significant interactions were observed in the co-administration with Atenolol or Nifedipine or both of the drugs. Cautions should be exercised in co-administration of Phenytoin, Tamoxifen, Tolbutamide, Warfarin & Fluvastatin with Clopidogrel for possible impairment in metabolism.

USE IN PREGNANCY AND LACTATION

There are no adequate & well-controlled studies of Clopidogrel in pregnant women. So Clopidogrel should be used in pregnancy only if clearly needed. Clopidogrel should not be prescribed to nursing mother unless absolutely necessary.

PRECAUTIONS

Avoid for first few days after myocardial infarction and for 7 days after ischemic stroke; not recommended in unstable angina, coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA) and patients at risk of increased bleeding from trauma, surgery or other pathological conditions; discontinue 7 days before elective surgery if antiplatelet effect is not desirable; administer with caution in liver impairment or renal impairment.

OVER DOSAGE

Overdose following Clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. Appropriate therapy should be considered if bleedings are observed. No antidote to the pharmacological activity of Clopidogrel has been found. If prompt correction of prolonged bleeding time is required, platelet transfusion may reverse the effects of Clopidogrel.

PHARMACEUTICAL PRECAUTION

Store in a cool and dry place, away from light. Keep out of reach of children.

HOW SUPPLIED

Each box contains 3x10's tablets in blister pack.

Manufactured by :



KEMIKO PHARMACEUTICALS LTD.

Bangladesh