For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

PLAVIX®

Clopidogrel Bisulphate Tablets

THERAPEUTIC CATEGORY

Antithrombotic - Platelet Aggregation Inhibitor

COMPOSITION

Each film coated tablet contains Clopidogrel Bisulphate I.P. equivalent to Clopidogrel 75mg

THERAPEUTIC INDICATIONS

Clopidogrel is indicated in adults for the secondary prevention of atherothrombotic events in:
Recent MI, Recent Stroke or Established Peripheral Arterial Disease
For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, clopidogrel has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.

Acute Coronary Syndrome

- For patients with non-ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave myocardial infarction [MI]) including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG, clopidogrel has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI, or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke or refractory ischemia.
- For patients with ST-segment elevation acute myocardial infarction, clopidogrel has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction or stroke. For patients with ST segment elevation acute myocardial infarction, in combination with ASA in patients undergoing percutaneous coronary intervention or medically treated patients eligible for thrombolytic/fibrinolytic therapy.

In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS)
Clopidogrel in combination with ASA is indicated in:

- Adult patients with moderate to high-risk TIA (ABCD2[1] score ≥4) or minor IS (NIHSS[2] ≤3) within 24 hours of either the TIA or IS event.

- Clopidogrel is indicated in adults for the prevention of atherothrombotic and thromboembolic events in:

Atrial Fibrillation
In patients with atrial fibrillation (AF) at increased risk of vascular events who can take vitamin K antagonist (VKA) therapy, VKA has been shown to be associated with a better clinical benefit than acetylsalicylic acid (ASA) alone or the combination of clopidogrel and ASA for the reduction of stroke.

In patients with atrial fibrillation who have at least one risk factor for vascular events and who cannot take VKA therapy (e.g., specific risk of bleeding, physician assessment that patient is unable to comply with INR (international normalised ratio) monitoring or that VKA use is inappropriate), clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke. Clopidogrel in combination with ASA has been shown to reduce the rate of the combined endpoint of stroke, myocardial infarction (MI), non-CNS systemic embolism, or vascular death, largely through a reduction in stroke (see Pharmacodynamics Section, Clinical Efficacy/Clinical Studies, Section).

DOSAGE AND ADMINISTRATION

Recent MI, Recent Stroke, or Established Peripheral Arterial Disease
Clopidogrel should be given as a single daily dose of 75 mg.

Acute Coronary Syndrome
For patients with non-ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave MI), clopidogrel should be initiated with a single 300-mg or 600 mg loading dose. A 600 mg loading dose may be considered in patients <75 years of age when percutaneous coronary intervention is intended

For patients with ST-segment elevation acute myocardial infarction

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[1] Age, Blood pressure, Clinical features, Duration, and Diabetes mellitus diagnosis

[2] National Institutes of Health Stroke Scale

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In medically treated patients eligible for thrombolytic/fibrinolytic therapy, the recommended dose of clopidogrel is 75 mg once daily, administered in combination with ASA, with or without thrombolytics.

Adult patients with moderate to high-risk TIA or minor IS
Adult patients with moderate to high-risk TIA (ABCD2 score ≥4) or minor IS (NIHSS ≤3) should be given a loading dose of clopidogrel 300 mg followed by clopidogrel 75 mg once daily and ASA (75 mg - 100 mg once daily).

Atrial Fibrillation
Clopidogrel should be given as a single daily dose of 75 mg. ASA (75-100 mg daily) should be initiated and continued in combination with clopidogrel

Pharmacogenomics
CYP2C19 poor metaboliser status is associated with diminished antiplatelet response to clopidogrel. Safety and effectiveness has not been established in paediatric population. No dosage adjustment in elderly, hepatic impairment and renal impairment.

SAFETY-RELATED INFORMATION

Contraindications: Hypersensitivity to the drug substance or to any of the excipients. Active pathological bleeding such as peptic ulcer and intracranial haemorrhage.

Precautions & Warnings: Caution in patients who may be at risk of increased bleeding from any conditions. If not desired, should be discontinued 5-7 days prior to surgery. Because of the increased risk of bleeding, the concomitant administration of warfarin with clopidogrel should be undertaken with caution. Clopidogrel prolongs bleeding time: caution when lesions with a propensity to bleed (gastrointestinal and intraocular). CYP2C19 poor metaboliser status is associated with diminished response to clopidogrel. Drugs that might induce gastrointestinal lesions should be used with caution in patients taking clopidogrel. Patients with recent transient ischaemic attack or stroke who are at high risk of recurrent ischaemic events, the combination of aspirin and clopidogrel has been shown to increase major bleeding. Thrombotic thrombocytopenic Purpura has been reported very rarely following the use of clopidogrel, sometimes after a short exposure. Acquired haemophilia has been reported following use of clopidogrel. Confirmed cases to be treated by specialists, and clopidogrel should be discontinued. In patients who are CYP2C19 poor metabolisers clopidogrel at recommended doses forms less of the active metabolite of clopidogrel and has a smaller effect on platelet function. Patients should be evaluated for history of hypersensitivity to another thienopyridine (such as ticlopidine, prasugrel) since cross-reactivity among thienopyridines has been reported. Caution needed in patients with severe renal and hepatic impairment. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine. The use of clopidogrel 600 mg loading dose is not recommended in patients with non-ST-segment elevation acute coronary syndrome and ≥75 years of age in view of limited data and due to increased bleeding risk in this population. There is no data to support the use of dual antiplatelet therapy in patients for whom treatment with carotid endarterectomy or intravascular thrombectomy is indicated, or in patients planned for thrombolysis or anticoagulant therapy. Dual antiplatelet therapy is not recommended in these situations.

Pregnancy: Should not be used unless there is a clear need.

Lactation: Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to a nursing woman.

Adverse Reactions Bleeding, including life threatening and fatal bleeding is the most commonly reported adverse reaction. Other common adverse reactions include dyspepsia, abdominal pain and diarrhoea.

For full prescribing information, refer to the company website www.sanofi.in

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