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
In adults for the 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 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 MI, 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.

DOSAGE AND ADMINISTRATION
Adults and elderly: single daily dose of 75 mg with or without food. In patient with NSTEMI, clopidogrel could be initiated with a single 300 mg loading dose continued at 75mg once a day. In STEMI, loading dose of 300mg may or may not be required. In ACS clopidogrel should be administered in combination with aspirin.
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. 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.
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, please contact Sanofi Healthcare India Pvt Ltd., Sanofi House C.T.S No-117-B, L& T Business Park, Saki Vihar Road, Powai, Mumbai 400 072- India

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