



SPMC

CLOPIDOGREL TABLETS USP 75mg

PRESENTATION:

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Packs: 500 Tablets bulk Pack

Each Circular 8.0mm diameter, Brownish pink colored, film coated biconvex tablets with “SPMC” or “SPC” letters on one side & score mark on reverse. Each film-coated tablet contains 75 mg of clopidogrel (as clopidogrel bisulfate).

INDICATIONS AND DOSE:

Prevention of atherothrombotic events in percutaneous coronary intervention (adjunct with aspirin) in patients not already on clopidogrel

Adult: Loading dose 300 mg, to be taken prior to the procedure, alternatively loading dose 600 mg, higher dose may produce a greater and more rapid inhibition of platelet aggregation
Transient ischaemic attack for patients with aspirin hypersensitivity, or those intolerant of aspirin despite the addition of a proton pump inhibitor
Acute ischaemic stroke for patients with aspirin hypersensitivity, or those intolerant of aspirin despite the addition of a proton pump inhibitor

Adult: 75 mg once daily
Prevention of atherothrombotic events in peripheral arterial disease or within 35 days of myocardial infarction, or within 6

months of ischaemic stroke

Adult: 75 mg once daily
Prevention of atherothrombotic events in acute coronary syndrome without ST-segment elevation (given with aspirin)

Adult: Initially 300mg then 75 mg daily for up to 12 months.

Prevention of atherothrombotic events in acute myocardial infarction with ST-segment elevation (given with aspirin)

Adult 18–75 years: Initially 300 mg, then 75 mg for at least 4 weeks

Adult 76 years and over: 75 mg daily for at least 4 weeks

Prevention of atherothrombotic and thromboembolic events in patients with atrial fibrillation and at least one risk factor for a vascular event (with aspirin) and for whom warfarin is unsuitable

Adult: 75 mg once daily

SIDE EFFECT:

Common or very common Diarrhoea. Gastrointestinal discomfort. haemorrhage. skin reactions

Uncommon Constipation. dizziness. eosinophilia. gastrointestinal disorders. headache. Intracranial haemorrhage. leucopenia. nausea. paraesthesia. thrombocytopenia. vomiting

Rare or very rare Acquired haemophilia. agranulocytosis. anaemia. angioedema. arthralgia. arthritis. bone marrow disorders. confusion. fever. glomerulonephritis. gynaecomastia. hallucination. hepatic disorders. hypersensitivity. hypotension. myalgia. neutropenia. pancreatitis. respiratory disorders. severe cutaneous adverse

reactions (SCARs). stomatitis. taste altered. ulcerative colitis. vasculitis. vertigo. wound haemorrhage
Frequency not known Kounis syndrome

INTERACTIONS:

Increased risk of bleeding with anticoagulants, other antiplatelets, NSAIDs, SSRIs, serotonin norepinephrine reuptake inhibitors. May reduce antiplatelet effect with CYP2C19 inhibitor including PPI (e.g. esomeprazole, omeprazole).

ALLERGY AND CROSS-SENSITIVITY

Caution with history of hypersensitivity reactions to thienopyridines (e.g. prasugrel).

CAUTION:

Discontinue 7 days before elective surgery if antiplatelet effect not desirable. patients at risk of increased bleeding from trauma, surgery, or other pathological conditions

PREGNANCY:

Advise avoid—no information available.

BREAST FEEDING:

Advise avoid

HEPATIC IMPAIRMENT:

Advise caution in moderate impairment in patients with an increased risk of bleeding—limited information available; avoid in severe impairment.

RENAL IMPAIRMENT:

caution.

CONTRA INDICATION:

Active bleeding. Hypersensitivity to the active substance Severe hepatic impairment. Active pathological bleeding such as peptic ulcer or intracranial haemorrhage.

OVERDOSAGE:

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.

STORAGE:

Keep tightly closed in a cool dry place. Protect from light. Keep all medicines away from children. Store below 30⁰ C.

Manufactured by
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