



Preclot

Clopidogrel 75 mg tablet

Presentation

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

Description

Clopidogrel is an inhibitor of ADP-induced platelet aggregation acting by direct inhibition of adenosine diphosphate (ADP) binding to its receptor and of the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex. Clopidogrel also inhibits platelet aggregation induced by agonists other than ADP by blocking the amplification of platelet activation by released A.P. Clopidogrel does not inhibit phosphodiesterase activity.

Indications

Prevention of atherosclerotic events in peripheral arterial disease, or within 35 days of myocardial infarction, or within 6 months of ischaemic stroke; prevention of atherosclerotic events in acute coronary syndrome without ST-segment elevation and in acute myocardial infarction with ST-segment elevation.

Dosage and Administration

Prevention of atherosclerotic events in peripheral arterial disease or after myocardial infarction or ischaemic stroke, 75 mg once daily. Acute coronary syndrome (without ST-segment elevation), initially 300 mg then 75 mg daily. Acute myocardial infarction (with ST-segment elevation), initially 300 mg then 75 mg daily; initial dose omitted if patient over 75 years.

Side Effects

Clopidogrel is generally well tolerated. Gastrointestinal disturbances and skin rashes are the most commonly reported side effects. Bloody dyscrasias, including neutropenia and thrombotic thrombocytopenic purpura, and hemorrhagic disorders have also occurred. There have been reports of hepatitis and cholestatic jaundice. Hyperlipidemia may occur during long-term therapy.

Contraindications

- Hypersensitivity to the drug substance or any component of the product.
- Active pathological bleeding such as peptic ulcer and intracranial hemorrhage.

Drug Interactions

Concomitant use of Heparin, Warfarin and NSAIDs with Clopidogrel should be undertaken with caution. Clopidogrel potentiates the effect of Aspirin on collagen-induced platelet aggregation. The safety of chronic concomitant administration of Aspirin and Clopidogrel has not been established.

Precautions

As with the other anti-platelet agents, should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions. If a patient is to undergo elective surgery and an anti-platelet effect is not desired, Clopidogrel should be discontinued at least 7 days prior to surgery. Clopidogrel should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions (such as Aspirin and other NSAIDs) should be used with caution in patients taking Clopidogrel. Clopidogrel should be used with caution in severe hepatic impaired patients. *Pregnancy:* There are no adequate and well-controlled studies in pregnant women. Clopidogrel should be used during pregnancy only if clearly needed. *Nursing mothers:* It is not known whether this drug is excreted into breast milk. Breast-feeding is not recommended while using this medicine. *Pediatric use:* Safety and effectiveness in the pediatric population have not been established.

Overdosage

No adverse events were reported after single oral administration of 600 mg (equivalent to 8 standard 75 mg tablets) of Clopidogrel to healthy subjects. The bleeding time was prolonged by a factor of 1.7 which is similar to that typically observed with the therapeutic dose of 75 mg of Clopidogrel per day.

Pharmaceutical Precautions

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

Commercial Pack

Preclot Tablet: Each box contains 3x10 tablets in blister pack.

Manufactured by :



POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH