

Only for the use of Medical Professionals

Clorel[®]

Clopidogrel

Presentation

Clorel[®] 75 mg Tablet: Each coated tablet contains Clopidogrel 75 mg as Bisulphate USP.

Description

Clorel[®] (Clopidogrel) is an inhibitor of platelet aggregation. Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP mediated activation of the glycoprotein GPIIb/ IIIa complex, thereby inhibiting platelet aggregation.

Uses

Clorel[®] is indicated for prevention of atherosclerotic events in patients with history of symptomatic atherosclerotic disease (ischaemic stroke, myocardial infarction or, established peripheral arterial disease).

Dosage and administration

Adults and elderly: Clopidogrel should be given as a single daily dose of 75 mg with or without food.

Children and adolescents: Safety and efficacy in subjects below the age of 18 have not been established.

Contraindications, warnings, etc.

The use of Clopidogrel is contraindicated for the following conditions:

- ◇ active bleeding
- ◇ breastfeeding

Drug interactions: Clopidogrel increases the risk of bleeding with NSAIDs and other antiplatelet drugs. It also enhances the effect of anticoagulants.

Precaution: Clopidogrel should be avoided for first few days after myocardial infarction and for 7 days after ischaemic stroke; patients at risk of increased

bleeding from trauma, surgery or other pathological conditions. Clopidogrel should be discontinued 7 days before elective surgery if antiplatelet effect is not desirable. Cautions should be taken in case of liver impairment, renal impairment and pregnancy.

Use in Pregnancy: There are no adequate studies of Clopidogrel in pregnant women.

Pediatric Use: Safety and efficacy in the Pediatric population have not been established.

Side effects: Haemorrhage (including gastrointestinal and intracranial); other side effects reported include abdominal discomfort, nausea, vomiting, diarrhoea, constipation, gastric and duodenal ulceration; headache, dizziness, vertigo, paresthesia, rash, pruritus, hepatic and biliary disorders, neutropenia, thrombotic thrombocytopenic purpura, isolated report of aplastic anaemia.

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/day. 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 Precautions

Store in cool and dry place protected from light. keep away from the reach of children.

Package quantities

Clorel® 75 mg Tablet: Carton of 30 tablets in blister.

Clorel® 75 mg Tablet: Carton of 10 tablets in blister (for export).

® Registered Trade Mark



ACI Limited

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