Inclaud®

Cilostazol

Description

Inclaud® is a preparation of Cilostazol which is a quinolinone derivative. Cilostazol inhibits cellular phosphodiesterase III (PDE III) and suppress cAMP degradation with a resultant increase in cAMP in platelets and blood vessels, leading to inhibition of platelet aggregation and vasodilation.

Indications

Inclaud® is indicated for the reduction of symptoms of intermittent claudication, as indicated by an increased walking distance.

Dosage and administration

The recommended dosage of Cilostazol is 100 mg twelve hourly taken at least half an hour before or two hours after breakfast and dinner. Patients may respond as early as 2 to 4 weeks after the initiation of therapy, but treatment for up to 12 weeks may be needed before a beneficial effect is experienced.
A dose of 50 mg twelve hourly should be considered during coadministration of such inhibitors of CYP3A4 as ketoconazole, itraconazole, erythromycin and diltiazem, and during coadministration of such inhibitors of CYP2C19.

Elderly

No overall differences in safety or effectiveness have not been observed in the elderly but greater sensitivity of some older individuals cannot be ruled out.

Children and adolescents

The safety and effectiveness of Cilostazol in paediatric patients have not been established.

Use in pregnancy and lactation

Cilostazol is a drug of pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Transfer of Cilostazol into milk has been reported in experimental animals. Because of the potential risk to nursing infants, a decision should be made to discontinue nursing or to discontinue Cilostazol.

Side-effects

The most commonly reported side-effects are headache, diarrhea, vomiting, dizziness & rhinitis. The infrequent side-effects at higher doses are-rash, vertigo, nausea, peripheral edema, flatulence etc.

Contraindications
Cilostazol is contraindicated in patients with known or suspected hypersensitivity to any of its components. It is also contraindicated in patients with congestive heart failure of any severity as well as in patients with haemostatic disorders or active pathologic bleeding, such as bleeding peptic ulcer and intracranial bleeding.

Precautions
There is limited information is available regarding the efficacy or safety of the concurrent use of Cilostazol and Clopidogrel, therefore caution is advised during coadministration of these two drugs and also advised for checking bleeding times during coadministration. Special caution is advised when Cilostazol is used in patients with severe renal impairment (creatinine clearance < 25 ml/min) as well as in patients with moderate or severe hepatic impairment.

Drug Interactions
Cilostazol could have pharmacodynamic interactions with other inhibitors of platelet function and pharmacokinetic interactions because of effects of other drugs on its metabolism by CYP3A4 such as ketoconazole, and erythromycin or inhibitors of CYP2C19. A reduced dose of Cilostazol should be considered when taken concomitantly with CYP3A4 or CYP2C19 inhibitors. Cilostazol does not appear to inhibit CYP3A4. There was no apparent increase in incidence of hemorrhagic adverse effects in patients taking Cilostazol and aspirin.

Overdosage
Information on acute overdosage with Cilostazol in humans is limited. Patient should be carefully observed and given supportive treatment. Since Cilostazol is highly protein-bound, it is unlikely that it can be efficiently removed by hemodialysis or peritoneal dialysis.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Inclaud® tablet: Each tablet contains Cilostazol USP 100 mg.

Package quantities
Inclaud® tablet: Carton of 20 tablets in blister.

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Narayanganj, Bangladesh