

Lirel®

Clopidogrel
75 mg

Presentation

Each film-coated tablet contains Clopidogrel bisulphate INN equivalent to Clopidogrel 75 mg.

Uses

Clopidogrel is indicated for the prevention of atherothrombotic events in- Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. Patients suffering from non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) in combination with aspirin.

Dosage & Administration

Adults and elderly: Clopidogrel should be given as a single daily dose of 75 mg with or without food. In patients with non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), clopidogrel treatment should be initiated with a single 300 mg loading dose and then continued at 75 mg once a day (with aspirin 75 mg - 325 mg daily). Since higher doses of aspirin were associated with higher bleeding risk it is recommended that the dose of aspirin should not be higher than 100 mg. The optimal duration of treatment has not been formally established. Clinical trial data support use up to 12 months, and the maximum benefit was seen at 3 months.

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

Contra-Indications

Hypersensitivity to the active substance or any component of the medicinal product. Severe liver impairment. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage. Breast-feeding.

Use in Pregnancy and Lactation

Pregnancy: Reproduction studies performed in rats and in rabbits revealed no evidence of impaired fertility or harm to the foetus due to clopidogrel. There are, however, no adequate and well-controlled studies in pregnant women. In view of the lack of data, clopidogrel is not recommended during pregnancy.

Lactation: Studies in rats have shown that clopidogrel and/or its metabolites are excreted in the milk. It is not known whether this medicinal product is excreted in human milk (see Contraindications).

Warnings and Precautions

Due to the risk of bleeding and haematological undesirable effects, blood cell count determination and/or other appropriate testing should be promptly considered whenever clinical symptoms suggestive of bleeding arise during the course of treatment. As with other antiplatelet agents, clopidogrel should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions and in patients receiving treatment with Aspirin, non-steroidal anti-inflammatory drugs, heparin, glycoprotein IIb/IIIa inhibitors or thrombolytics. In view of the lack of data, in patients with acute myocardial infarction with ST-segment elevation, clopidogrel therapy should not be initiated within the first few days following myocardial infarction. In view of the lack of data, clopidogrel cannot be recommended in acute ischaemic stroke (less than 7 days).

Side Effects

Bleeding: Some cases were reported with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage); serious cases of skin bleeding (purpura), musculo-skeletal bleeding (haemarthrosis, haematoma), eye bleeding (conjunctival, ocular, retinal), epistaxis, respiratory tract bleeding (haemoptysis, pulmonary hemorrhage), haematuria and haemorrhage of operative wound have been reported; cases of serious hemorrhage have been reported in patients taking clopidogrel concomitantly with aspirin or clopidogrel with aspirin and heparin. Haematological: Very rare cases of Thrombotic Thrombocytopenic Purpura (TTP) (1/200,000 exposed patients) have been reported. Allergic disorders: Hypersensitivity reactions have been reported: these mainly include skin reactions (macular or erythematous rash, urticaria, bullous eruption, erythema multiforme) and/or pruritus. Very rare cases of bronchospasm, angioedema, anaphylactoid reactions, fever, arthralgia and arthritis have been observed. Others: Very rare cases of taste disorders, confusion and hallucinations have been observed.

Commercial Pack

Lirel® : Each box containing 2 x 10 tablets in alu-alu pack.

Manufactured by:
 **Silva**
Pharmaceuticals Limited
Majidde. Noakhali, Bangladesh