

Odrel®

Tablet

Description

Odrel (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. Each tablet contains Clopidogrel Bisulphate INN equivalent to 75 mg Clopidogrel.

Indications

Odrel is indicated for the reduction of atherosclerotic events (myocardial infarction, stroke and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction or established peripheral arterial disease.

Dosage and Administration

The recommended dose of Odrel is 75 mg once daily with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease.

Contraindication

The use of Odrel is contraindicated in the following conditions :

i) Hypersensitivity to any component of the product and ii) Active pathological bleeding such as peptic ulcer or intracranial haemorrhage.

Precautions

As with other antiplatelet agents, Odrel 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 surgery and an antiplatelet effect is not desired, Odrel should be discontinued 7 days prior to surgery.

Odrel prolongs the bleeding time. Patients should be told that it might take them longer than usual to stop bleeding when they take Odrel and that they should report any unusual bleeding to their physician.

Drug Interactions

Concomitant administration of Clopidogrel with NSAIDs, Warfarin or Heparin should be undertaken with caution.

Side Effects

The most common clinically important side effects are pruritus, purpura, diarrhoea and rash. Infrequent events include intracranial haemorrhage (0.4%) and severe neutropaenia (0.04%).

Use in Special Populations

Hepatic impaired patients : Odrel should be used with caution in this population.

Paediatric patients : Safety and effectiveness in the paediatric population have not been established.

Pregnancy : Animal studies revealed no evidence of impaired fertility or foetotoxicity due to Clopidogrel. There are, however, no adequate and well controlled studies in pregnant women. Because animal studies are not always predictive of a human response, Odrel should be used during pregnancy only if clearly needed.

Commercial Pack

Odrel® Tablet : Box containing 10 tablets in 1 x 10's blister strip. Each tablets contains Clopidogrel Bisulphate INN equivalent to 75 mg of Clopidogrel.