Cosgrel® (Tablets)

1276
Ref. No.:INS276/04.18

Clopidogrel Bisulfate

Antiplatelet

COSGREL® TABLETS 75MG (FILM COATED)

PRESENTATION:
Cosgrel® Tablets 75mg: Light crimson, circular, biconvex film coated tablet embossed 'C' on one side and plain on the other side. Each film coated tablet contains: Clopidogrel Bisulfate equivalent to Clopidogrel 75mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:
Clopidogrel is a thienopyridine antiplatelet drug used in thromboembolic disorders. It is an analogue of ticlopidine and acts by inhibiting adenosine diphosphate-mediated platelet aggregation.

Pharmacokinetics:
Clopidogrel is rapidly but incompletely absorbed after oral doses; absorption appears to be at least 50%. It is a prodrug and is extensively metabolised in the liver, mainly to the inactive carboxylic acid derivative. The active metabolite appears to be a thiol derivative but has not been identified in plasma. Clopidogrel and the carboxylic acid derivative are highly protein bound. Clopidogrel and its metabolites are excreted in urine and in faeces; about 50% of an oral dose is recovered from the urine and about 46% from the faeces.

USES:
It is given prophylactically as an alternative to aspirin in patients at risk of thromboembolic disorders such as myocardial infarction peripheral arterial disease, and stroke. Cosgrel® is also used with aspirin in the management of unstable angina, and has been tried as an alternative to ticlopidine in patients undergoing coronary stenting.

DOSAGE AND ADMINISTRATION:
- Prevention of atherothrombotic events in peripheral arterial disease or after myocardial infarction or ischaemic stroke, 75mg once daily.
- Acute coronary syndrome (without ST-segment elevation) initially 300mg then 75mg daily (with aspirin)
- Acute myocardial infarction (with ST-segment elevation) initially 300mg then 75mg daily (with aspirin); initial dose omitted if patient over 75years.
- Prevention of atherothrombotic and thromboembolic events in patients with atrial fibrillation (with aspirin), 75mg once daily.

CONTRA-INDICATIONS AND WARNINGS:
Known hypersensitivity to Clopidogrel or any ingredient in the formulation. Presence of active pathological bleeding.
Precautions:
Cosgrel® should not be administered to patients with haematopoietic disorders such as neutropenia or thrombocytopenia, haemorrhagic diathesis or other haemorrhagic disorders associated with a prolonged bleeding time, or conditions with an increased risk of bleeding such as peptic ulcer disease, acute cerebral haemorrhage, or severe liver dysfunction. Full blood counts should be performed before starting treatment and every 2 weeks during the first 3 months of therapy. If Cosgrel® is discontinued during this period, a full blood count should be performed within 2 weeks of stopping treatment. Consideration should be given to stopping Cosgrel® therapy 10 to 14 days before elective surgery.

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Adverse Effects:
Gastrointestinal disturbances, skin rashes, and bleeding are the most commonly reported adverse effects associated with Cosgrel® therapy. Blood dyscrasias, including neutropenia, thrombotic thrombocytopenic purpura, and aplastic anaemia, have also occurred. There have been reports of hepatitis and cholestatic jaundice. Blood-lipid concentrations may increase during long-term therapy.

Interactions:
Cosgrel® should be used with caution in patients receiving other drugs that increase the risk of bleeding, including anticoagulants, other antiplatelets, and NSAIDs.

Pregnancy and breastfeeding:
It is preferable not to take this product during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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COSMOS

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