DEPLATT

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for DEPLATT (Clopidogrel 75mg and 150mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: - Clopidogrel is a prodrug, one of whose metabolites is an inhibitor of platelet aggregation. Clopidogrel must be metabolised by CYP450 enzymes to produce the active metabolite that inhibits platelet aggregation.

INDICATION: - For the treatment of atherosclerotic events (myocardial infarction, stroke and vascular death) in patients with atherosclerosis.

DOSAGE AND ADMINISTRATION: Should be given as a single daily dose of 75 mg. Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction): Should be initiated with a single 300-mg loading dose and then continued at 75 mg once a day (with acetylsalicylic acid (ASA) 75 mg-325 mg daily). ST segment elevation acute myocardial infarction: Should be given as a single daily dose of 75 mg initiated with a 300-mg loading dose in combination with ASA and with or without thrombolytics. It may be given with or without food. For oral use only.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, severe hepatic impairment, active pathological bleeding such as peptic ulcer or intracranial haemorrhage.

WARNINGS & PRECAUTIONS: Bleeding and haematological disorder, thrombotic thrombocytopenic purpura (TTP), acquired haemophilia, recent ischaemic stroke, cross-reactions among thienopyridines.

DRUG INTERACTIONS: Oral anticoagulants, Glycoprotein IIb/IIIa inhibitors: clopidogrel should be used with caution in patients who receive concomitant glycoprotein IIb/IIIa inhibitors., Acetylsalicylic acid (ASA), thrombolytics, NSAIDs, SSRIs, medicinal products that inhibit CYP2C19 include omeprazole and esomeprazole, fluvoxamine, fluoxetine, moclobemide, voriconazole, fluconazole, ticlopidine, ciprofloxacin, cimetidine, carbamazepine, oxcarbazepine and chloramphenicol.

ADVERSE REACTIONS: Haematoma, epistaxis, gastrointestinal haemorrhage, diarrhoea, abdominal pain, dyspepsia, bruising, bleeding at puncture site, thrombocytopenia, leucopenia, eosinophilia, intracranial bleeding (some cases werereported with fatal outcome), headache, paraesthesia, dizziness, eye bleeding (conjunctival, ocular, retinal), gastric ulcer and duodenal ulcer, gastritis, vomiting, nausea, constipation, flatulence, rash, pruritus, skin bleeding (purpura), haematuria, bleeding time prolonged, neutrophil count decreased, platelet count decreased, neutropenia, including severe neutropenia, vertigo, retroperitoneal haemorrhage, gynaecomastia.

MARKETED BY:



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(Additional information is available on request)