

DEPLATT A

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

Abbreviated Prescribing information for DEPLATT (Clopidogrel 75mg and Aspirin 75 or Clopidogrel 75mg and Aspirin 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. Aspirin is an anti thrombotic agent used in the prophylaxis of angina pectoris and myocardial infarction.

INDICATION: - For the treatment of angina, myocardial infarction and stroke.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet once daily taken with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease. Swallow whole tablet. Do not crush or chew.

CONTRAINDICATION: **Clopidogrel:** Contraindicated in patients with active bleeding and hypersensitivity to clopidogrel or any component of the product. **Aspirin:** Active or history of peptic ulceration, haemophilia and other coagulopathies including hypoprothrombinaemia, gout and hypersensitivity to NSAIDs.

WARNINGS & PRECAUTIONS: **Clopidogrel:** Diminished antiplatelet activity due to impaired CYP2C19 function, avoid concomitant use of proton pump inhibitors, increase the risk of bleeding. Premature discontinuation of clopidogrel may increase the risk of cardiovascular events. Thrombotic thrombocytopenic purpura (TTP) and cross-reactions among thienopyridines. **Aspirin:** Caution should be exercised in patients with allergic disease, impairment of hepatic or renal function, bronchospasm or induce attacks of asthma. Caution should be taken in patients with glucose-6-phosphate dehydrogenase deficiency as haemolytic anaemia may occur. Aspirin prolongs bleeding time. Salicylates should not be used in patients with a history of coagulation abnormalities as they may also induce gastro-intestinal haemorrhage, occasionally major. Aspirin should not be taken by patients with a stomach ulcer or a history of stomach ulcers. Caution should be taken in elderly patients, paediatric patients and Reye's syndrome in children, pregnancy and lactating women.

DRUG INTERACTIONS: **Clopidogrel:** CYP2C19 inhibitors, proton pump inhibitors, NSAIDs, warfarin (CYP2C9 Substrates), SSRIs and SNRIs, propranolol, antacids. **Aspirin:** Anticoagulants, corticosteroids, carbonic anhydrase inhibitors, antacids and adsorbents, mifepristone, antimetabolites, antibacterials, alcohol, ACE inhibitors, anti-epileptics, diuretics, hypoglycaemic agents, leukotriene antagonists, uricosurics, zafirlukast,

ADVERSE REACTIONS: **clopidogrel:** Bleeding, agranulocytosis, aplastic anemia/pancytopenia, thrombotic thrombocytopenic purpura (TTP), acquired hemophilia, eye (conjunctival, ocular, retinal) bleeding, gastrointestinal and retroperitoneal hemorrhage with fatal outcome, colitis, pancreatitis, stomatitis, gastric/duodenal ulcer, diarrhea, fever, hemorrhage of operative wound, acute liver failure, hepatitis (non-infectious), abnormal liver function test, hypersensitivity reactions, anaphylactoid reactions, serum sickness, musculoskeletal bleeding, myalgia, arthralgia, arthritis, fatal intracranial

bleeding, headache, confusion, hallucinations, increased creatinine levels maculopapular, erythematous, urticaria, bullous dermatitis, eczema, toxic epidermal necrolysis, stevens-johnson syndrome, drug rash with eosinophilia and systemic symptoms, erythema multiforme, lichen planus, generalized pruritus, vasculitis, urticaria and angioedema **Aspirin:** hypoprothrombinaemia, thrombocytopenia, hypersensitivity reactions, tinnitus and urate kidney stones.

MARKETED BY:



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(Additional information is available on request)