

DEPLATT CV 20 FORTE

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

Abbreviated prescribing information for Deplatt CV 20 Forte (clopidogrel 75mg, atorvastatin 20mg and aspirin 150mg) [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. Atorvastatin lowers plasma cholesterol and lipoprotein serum concentrations by inhibiting HMGCoA Reductase. Aspirin is an anti thrombotic agent used in the prophylaxis of angina pectoris and myocardial infarction. **INDICATION:** - In the treatment of patients with PCI (Percutaneous coronary intervention) and myocardial infarction (MI).

DOSAGE AND ADMINISTRATION: Clopidogrel: - It should be given as a single daily dose of 75 mg. **Atorvastatin:** - The usual starting dose is 10 mg once a day. Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day. **Aspirin:** - Aspirin 75 mg is for oral administration to adults only.

CONTRAINDICATION: Contraindicated in patients with active bleeding, hypersensitivity to any of the active substance or any component of the product, active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal, during pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures, active or history of peptic ulceration, haemophilia and other coagulopathies including hypoprothrombinaemia, gout and hypersensitivity to NSAIDs.

WARNINGS & PRECAUTIONS: Clopidogrel: Use cautiously or stop the Deplatt CV 20 Forte in patient with Bleeding and haematological disorders, Thrombotic Thrombocytopenic Purpura (TTP), acquired haemophilia, recent ischaemic stroke, poor CYP2C19 metabolisers, cross-reactions among thienopyridines, renal impairment and Hepatic impairment. **Atorvastatin:** - Used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. **Aspirin:** should not be given to children aged under 16 years unless specifically indicated (e.g. for Kawasaki's disease). It also decreases platelet adhesiveness and increases bleeding time resulting in haemorrhagic effects.

DRUG INTERACTIONS: Clopidogrel: Oral anticoagulants, glycoprotein IIb/IIIa inhibitors, acetylsalicylic acid, heparin, thrombolytics, NSAIDs, CYP2C19 inhibitors, proton pump inhibitors, NSAIDs, warfarin (CYP2C9 Substrates), SSRIs and SNRIs, propranolol and antacids. **Atorvastatin:-** CYP3A4 inhibitors (e.g. erythromycin, diltiazem, verapamil and fluconazole), inducers of cytochrome P450 3A (e.g. efavirenz, rifampin, St. John's Wort), transport proteins (e.g. ciclosporin), fibrates, ezetimibe, colestipol, colchicines, digoxin, oral contraceptive, warfarin **Aspirin:** Anticoagulants, corticosteroids, carbonic anhydrase inhibitors, antacids and adsorbents, mifepristone, antimetabolites, antibacterials, alcohol, ACE inhibitors, anti-epileptics, diuretics, hypoglycaemic agents, leukotriene antagonists, uricosurics and zafirlukast.

ADVERSE REACTIONS: Thrombocytopenia, leucopenia, eosinophilia, intracranial bleeding, headache, paraesthesia, dizziness, eye bleeding, haematoma, epistaxis, gastrointestinal haemorrhage, diarrhoea, abdominal pain, dyspepsia, gastric ulcer and duodenal ulcer, gastritis, vomiting, nausea, constipation, flatulence, bruising, rash, pruritus, skin bleeding (purpura), gynaecomastia, haematuria, bleeding time prolonged, neutrophil count decreased, platelet count decreased nasopharyngitis, thrombocytopenia, allergic reactions, hyperglycaemia, weight gain, hypoglycaemia, anorexia, nightmare, insomnia, headache, paraesthesia, hypoesthesia, dysgeusia, amnesia, peripheral neuropathy, vision blurred, visual disturbance, tinnitus, pharyngolaryngeal pain, dyspepsia, hepatitis, cholestasis, alopecia, myalgia, rhabdomyolysis, arthralgia, pain in extremity, muscle spasms, joint swelling, muscle fatigue, liver function test abnormal and blood creatine kinase increased, hypoprothrombinaemia, tinnitus and urate kidney stones.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)