**DEPLATT-CV**

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

Abbreviated Prescribing information for **DEPLATT-CV** [Clopidogrel Bisulphate with Atorvastatin and Aspirin Capsules] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: *Clopidogrel:* Clopidogrel is a prodrug. Its active metabolite selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet $P2Y_{12}$ receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. *Atorvastatin:* Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme responsible for the conversion of 3-hydroxy-3-methyl-glutaryl-coenzyme. *Aspirin:* Aspirin has analgesic, antipyretic and anti-inflammatory actions. It produces substantial inhibition of ADP-induced platelet aggregation. **INDICATION**: In the treatment of patients with PCI (Precutaneous coronary intervention) and myocardial infarction (MI). **DOSAGE AND ADMINISTRATION**: Hard gelatin capsule. For oral use. It may be given with or without food. *Clopidogrel:* For Adults and older people, it should be given as a single daily dose of 75 mg. *Atorvastatin:* The usual starting dose is 10 mg once a day. The maximum dose is 80 mg once a day. *Aspirin:* Aspirin 75 mg is for adults only. **CONTRAINDICATION:** In patients with hypersensitivity to any of the active substance or to any of the excipients of the capsule, patients with severe hepatic impairment, active pathological bleeding. Atorvastatin is also contraindicated during pregnancy, while breast-feeding and in women of child-bearing potential. Aspirin is contraindicated in patients with hypoprothrombinaemia, haemophilia and active peptic ulceration. **WARNINGS & PRECAUTIONS**: *Clopidogrel:* Due to the risk of bleeding, haematological adverse reactions and Thrombotic Thrombocytopenic Purpura (TTP) may occur. Since clopidogrel is metabolised to its active metabolite partly by CYP2C19, use of medicinal products that inhibit the activity of this enzyme would be expected to result in reduced drug levels. Patients should be evaluated for history of hypersensitivity to thienopyridines. Dose modification should be required for the patients with renal and hepatic impairment. *Atorvastatin:* It should be used with caution in patients who consume alcohol. It may cause myalgia, myositis and myopathy that may progress to rhabdomyolysis. It may also elevate creatine kinase (CK) levels. A potent inhibitor of CYP3A4 or transport proteins may increase the plasma concentration of atorvastatin. *Aspirin:* Reye's syndrome may be caused by aspirin hence it should not be given to children aged under 16 years unless specifically indicated. It may increase bleeding time and precipitate bronchospasm or induce attacks of asthma. **DRUG INTERACTIONS**: *Clopidogrel:* It may interact with oral anticoagulants, glycoprotein IIb/IIIa inhibitors, heparin, thrombolytics, NSAIDs, SSRIs and Proton Pump Inhibitors. *Atorvastatin:* It is metabolized by CYP3A4, hence inducers and inhibitors of the CYP3A4 may elevate drug level. It may interact with Transport protein inhibitors like ciclosporin, digoxin, oral contraceptives and warfarin. Use with gemfibrozil / fibric acid derivatives and ezetimibe may cause muscle related events. *Aspirin:* It may inhibit the uricosuric effect of probenecid and may increase the toxicity of sulphonamides. It may interact with heparin, corticosteroids, NSAIDs and carbonic anhydrase inhibitors. **ADVERSE REACTIONS**: *Clopidogrel:* bleeding disorders, haematoma, gastrointestinal haemorrhage, abdominal pain, dyspepsia. *Atorvastatin:* pharyngolaryngeal pain, epistaxis, allergic reactions, hyperglycaemia, constipation, myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain, liver function test abnormal, blood CK increased, abdominal pain. *Aspirin:* gastrointestinal irritation, anaemia, epistaxis, haematuria, purpura, gastrointestinal bleeding, haematoma and cerebral haemorrhage.

**MARKETED BY:**


TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)