

DEPLATT CV 40

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

Abbreviated Prescribing information for DEPLATT CV 40

(ATORVASTATIN, CLOPIDOGREL & ASPIRIN CAPSULES) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: **Atorvastatin:** It is a selective, competitive inhibitor of 3-hydroxy-3methylglutaryl-coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme that converts 3-HMG-CoA to mevalonate, a precursor of sterols, including cholesterol. Cholesterol and triglycerides (TG) circulate in the bloodstream as part of lipoprotein complexes. With ultracentrifugation, these complexes separate into high-density lipoprotein (HDL), intermediate-density lipoprotein (IDL), low-density lipoprotein (LDL) and very-low-density lipoprotein (VLDL) fractions. **Clopidogrel:** It is an inhibitor of platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y₁₂ class of ADP receptors on platelets. **Aspirin:** It is a more potent inhibitor of both prostaglandin synthesis and platelet aggregation than other salicylic acid derivatives. The differences in activity between aspirin and salicylic acid are thought to be due to the acetyl group on the aspirin molecule. This acetyl group is responsible for the inactivation of cyclooxygenase via acetylation. Aspirin affects platelet aggregation by irreversibly inhibiting prostaglandin cyclo-oxygenase. This effect lasts for the life of the platelet and prevents the formation of the platelet-aggregating factor thromboxane A₂.

INDICATIONS: In the treatment of patients with PCI (Percutaneous coronary intervention) and myocardial infarction (MI).

DOSAGE AND ADMINISTRATION: Atorvastatin 40 mg, Clopidogrel 75 mg & Aspirin 75 mg Capsules. The recommended dosage is once daily or as directed by the Physician. Capsule should be taken orally.

CONTRAINDICATION **Atorvastatin** is contraindicated in patients with hypersensitivity, active liver disease, myopathy, during pregnancy, breast-feeding and women of child-bearing potential not using appropriate contraceptive measures. **Clopidogrel** contraindicated with Hypersensitivity, Severe hepatic impairment, Active bleeding such as peptic ulcer or intracranial haemorrhage. **Aspirin:** Hypersensitivity to salicylic acid compounds or prostaglandin synthetase inhibitors, Active, or history of peptic ulceration and/or gastric/intestinal haemorrhage, or other kinds of bleeding such as cerebrovascular haemorrhages, Haemorrhagic diathesis; coagulation disorders such as haemophilia, thrombocytopenia or concurrent anticoagulant therapy, gout, hepatic impairment, Severe renal impairment.

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)