DEPLATT AV

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

Abbreviated Prescribing information for DEPLATT AV [Atorvastatin and Clopidogrel Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Atorvastatin***- Atorvastatin works by selectively inhibiting HMG-CoA reductase, the enzyme responsible for converting HMG-CoA to mevalonate, a precursor of cholesterol. This inhibition reduces cholesterol synthesis in the liver. In response, the liver increases the expression of LDL receptors to capture more LDL particles from the bloodstream, lowering LDL-cholesterol (LDL-C) levels. This helps reduce the risk of atherosclerosis and cardiovascular disease. ***Clopidogrel-*** Clopidogrel 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.

INDICATION: For 10mg and 20 mg it is indicated for post coronary intervention and acute syndrome. For 40mg it is indicated for the treatment of dyslipidemia associated with artherosclerotic arterial disease with risk of myocardial infarction, stroke, or peripheral vascular disease.

DOSAGE AND ADMINISTRATION: Patients should be placed on an appropriate lipid-lowering diet before receiving Deplatt AV and should continue this diet during treatment. The recommended dosage is one Tablet once daily. The dose of atorvastatin can be individualized according to baseline LDL-C levels, the goal of therapy and patient response. The usual starting dose is 10mg once daily. Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80mg once daily. The dosage of clopidogrel in unstable angina (UA) / Non-ST-elevated myocardial infarction (NSTEMI) is 75 mg daily after a single loading dose. In patients with STEMI, recent MI, stroke or peripheral artery disease, the recommended dose of clopidogrel is 75 mg once daily. Avoid using omeprazole or esomeprazole with Deplatt AV. Omeprazole and esomeprazole significantly reduce the antiplatelet activity of clopidogrel. When concomitant administration of a PPI is required, consider using another acid-reducing agent with minimal or no CYP2C19 inhibitory effect on the formation of clopidogrel active metabolite.

CONTRAINDICATION: ***Atorvastatin***- a) Hypersensitivity to the active substance or to any of the excipients of this medication. b) active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal. c) myopathy d) during pregnancy e) while breastfeeding f) in women of child bearing potential not using appropriate contraceptive measures. ***Clopidogrel-*** a) hypersensitivity to the active substance or to any of the excipients b) severe hepatic impairment c) active pathological bleeding such as peptic ulcer or intracranial haemorrhage.

WARNINGS & PRECAUTIONS: ***Atorvastatin-*** Atorvastatin can cause liver and muscle-related side effects, including myopathy and rhabdomyolysis, requiring regular monitoring of liver enzymes and creatine kinase (CK) levels. It should be used with caution in patients with risk factors such as renal impairment, liver disease, or a history of muscular disorders. ***Clopidogrel***- Clopidogrel can increase the risk of bleeding and hematological disorders, requiring careful monitoring, especially in patients with risk factors or undergoing surgery. It should be used cautiously in those with hepatic or renal impairment, and its effectiveness may be reduced in patients who are poor CYP2C19 metabolisers.

DRUG INTERACTIONS: ***Atorvastatin***- Atorvastatin is metabolized by the cytochrome P450 3A4 enzyme, so concurrent use with CYP3A4 inhibitors (e.g., cyclosporine, macrolides like erythromycin, azole antifungals, HIV protease inhibitors) can increase atorvastatin plasma levels, heightening the risk of myopathy or rhabdomyolysis. Grapefruit juice, a CYP3A4 inhibitor, can similarly elevate atorvastatin levels, particularly with large amounts. Fibrates, especially gemfibrozil, can also increase atorvastatin's concentration, increasing the risk of muscle-related side effects. Additionally, atorvastatin may interact with digoxin, oral contraceptives, warfarin, and antacids, affecting their plasma levels or therapeutic effects, requiring close monitoring. ***Clopidogrel***- Co-administration of clopidogrel with CYP2C19 inhibitors, like omeprazole or esomeprazole, reduces the formation of its active metabolite, decreasing its antiplatelet effect and increasing cardiovascular risk. Using clopidogrel with NSAIDs raises the risk of gastrointestinal bleeding, while concurrent use with warfarin enhances bleeding risk due to their independent effects on hemostasis, despite no significant change in warfarin’s pharmacokinetics. SSRIs

and SNRIs, which affect platelet function, can further increase bleeding risk when combined with clopidogrel. Additionally, clopidogrel inhibits CYP2C8, increasing systemic exposure to drugs metabolized by this enzyme, such as repaglinide, which requires dose adjustments to avoid hypoglycemia.

ADVERSE REACTIONS: ***Atorvastatin-*** Abdominal pain, constipation, flatulence, dyspepsia, nausea, myalgia, skin rash, insomnia, headache, dizziness, anorexia, vomiting, thrombocytopenia, muscle cramps, myopathy, hepatotoxicity, impotence, weight gain, hepatitis, cholestatic jaundice, myositis, rhabdomyolysis, tendon rupture, hepatic failure, anaphylaxis, visual disturbance, rhabdomyolysis, Stevens-Johnson syndrome. ***Clopidogrel-*** Hematoma, epistaxis, gastrointestinal hemorrhage, thrombocytopenia, leucopenia, eye bleeding, gastric/duodenal ulcers, rash, pruritus, neutropenia, retroperitoneal hemorrhage, vertigo, bruising, TTP, acute liver failure, respiratory tract bleeding, severe bleeding, skin conditions like toxic epidermal necrolysis.

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TORRENT PHARMACEUTICALS LTD.

IN/DEPLATT AV/JUL 2026/02/ABPI