

Composition : Amlodipine + Atorvastatin; (5mg+10mg) Tablet.

Indications : This drug is indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate. Amlodipine is used to treat hypertension, chronic stable angina, vasospastic angina. Atorvastatin is a lipid lowering agent and it is used to treat hypercholesterolemia.

Dosage and administration : Dosage of this drug must be individualized on the basis of both effectiveness and tolerance for each individual component in the treatment of hypertension, angina and hyperlipidemia. This drug may be substituted for its individually titrated components for patients on amlodipine and atorvastatin.

Amlodipine: The usual initial antihypertensive oral dose is 5mg once daily with a maximum dose of 10mg once daily. Elderly individuals or patients with hepatic insufficiency may be started on 2.5mg once daily dose and this dose may be used when adding Amlodipine to other antihypertensive therapy. Dosage should be adjusted according to each patient's need.

Atorvastatin: Adults: The patient should be placed on a standard cholesterol-lowering diet before receiving Atorvastatin and should continue on this diet during treatment with Atorvastatin.

Hypercholesterolemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb): The recommended starting dose of Atorvastatin is 10mg daily. The dosage range is 10 to 80 mg once daily. **Homozygous Familial Hypercholesterolemia:** The dosage of Atorvastatin in patients with homozygous FH is 10 to 80 mg daily. **Patients with renal insufficiency:** Renal disease has no influence on the plasma concentrations or lipid effects of Atorvastatin; thus no adjustment of dose is required.

Divastin Plus

Film Coated Tablet

Contraindication : It is contraindicated in patients who are hypersensitive to any component of this product.

Side effects : In general, treatment with this drug is well tolerated. The most frequent side effects related to amlodipine are headache and edema. The most frequent side effects related to atorvastatin are constipation, flatulence, dyspepsia and abdominal pain.

Precautions : It should be used with caution in patients with impaired renal function, heart problem and impaired hepatic function.

Use in Pregnancy and lactation : This drug should be administered to women of bearing age only when such patients and lactation are highly unlikely to conceive and have been informed of the potential hazards.

Drug interactions : No drug interaction studies have been conducted with this drug and other drugs, although studies have been conducted in the individual amlodipine and atorvastatin components. No significant drug interactions were reported in studies in which amlodipine was co-administered with digoxin, phenytoin, warfarin, cimetidine, antacid and indomethacin. The risk of myopathy during treatment with drugs of the HMG-Co-A reductase class is increased with concurrent administration of cyclosporine, fibric acid derivatives, niacin, erythromycin, azole antifungals.

Packing :

Divastin Plus : 3 x 10's tablets in alu-alu blister pack.