ATV Plus

Atorvastatin 10 mg and Amlodipine 5 mg

DESCRIPTION
This tablet combines the long-acting calcium channel blocker Amlodipine Besilate with the synthetic lipid-altering agent Atorvastatin Calcium.

MECHANISM OF ACTION
It is a combination of two drugs, a Dihydropyridine Calcium antagonist (calcium-channel blocker) Amlodipine (antihypertensive/antianginal agent) and an HMG-CoA reductase inhibitor Atorvastatin (cholesterol lowering agent). Amlodipine inhibits the transmembrane influx of Calcium ions into vascular smooth muscle and cardiac muscle. Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase (statin), the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol.

INDICATIONS AND USAGE
It is indicated in patients for whom treatment with both Amlodipine and Atorvastatin is appropriate.

Amlodipine
1. Hypertension
2. Coronary Artery Disease (CAD)
   * Chronic Stable Angina
   * Vasospastic Angina (Prinzmetal's or Variant Angina)
   * Angiographically Documented CAD

Atorvastatin
Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended, as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD (Coronary Heart Disease) or multiple risk factors for CHD (Coronary Heart Disease), the Atorvastatin component can be started simultaneously with diet.

1. Prevention of Cardiovascular Diseases
In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDLC or a family history of early coronary heart disease, Atorvastatin is indicated to
* Reduce the risk of myocardial infarction
* Reduce the risk of stroke
* Reduce the risk for revascularization procedures and angina

In patients with type 2 diabetes and without clinically evident coronary heart disease but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, it is indicated to
* Reduce the risk of myocardial infarction
* Reduce the risk of stroke

In patients with clinically evident coronary heart disease, it is indicated to
* Reduce the risk of non-fatal myocardial infarction
* Reduce the risk of fatal and non-fatal stroke
* Reduce the risk for revascularization procedures
* Reduce the risk of hospitalization for CHF (Congestive Heart Failure)
* Reduce the risk of angina

2. Heterozygous Familial and Nonfamilial Hyperlipidemia
Atorvastatin is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, apo B and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb).

3. Elevated Serum TG Levels
Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV).

4. Primary Dysbetalipoproteinemia
Atorvastatin is indicated for the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet.

5. Homozygous Familial Hypercholesterolemia
Atorvastatin is indicated to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

6. Pediatric Patients
Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
a. LDL-C remains >_190 mg/dL or
b. LDL-C remains >_160 mg/dL and
   * There is a positive family history of premature cardiovascular disease or
   * Two or more other CVD risk factors are present in the pediatric patients.

DOSAGE AND ADMINISTRATION
It must be individualized on the basis of both effectiveness and tolerance for each individual component in the treatment of hypertension/angina and hyperlipidemia.

Amlodipine (Hypertension or angina)
Adults: The usual initial antihypertensive oral dose of Amlodipine is 5 mg once daily with a maximum dose of 10 mg once daily. The recommended dose of Amlodipine for chronic stable or vasospastic angina is 5-10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. The recommended dose range of Amlodipine for patients with coronary artery disease is 5-10 mg once daily.
Children: The effective antihypertensive oral dose of Amlodipine in pediatric patients ages 6-17 years is 2.5 mg to 5 mg once daily.

Atorvastatin (Hyperlipidemia)
Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb)
The recommended starting dose of Atorvastatin is 10 or 20 mg once daily.
The dosage range of Atorvastatin is 10 to 80 mg once daily. Atorvastatin can be administered as a single dose at any time of the day, with or without food.
Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age)
The recommended starting dose of Atorvastatin is 10 mg/day; the maximum recommended dose is 20 mg/day.
Homozygous Familial Hypercholesterolemia
The dosage of Atorvastatin in patients with homozygous FH is 10 to 80 mg daily.

CONTRAINDICATIONS
It is contraindicated in patients with active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels, in patients with known hypersensitivity to any component of this medication, women who are pregnant or may become pregnant and nursing mother.

SIDE EFFECTS
Common side effects of this medicine include: headache, dizziness, tiredness, extreme sleepiness, stomach pain, nausea, upset stomach, diarrhea, swelling of legs or ankles (edema), hot or warm feeling in face (flushing), irregular heartbeat (arrhythmia), very fast heartbeat (heart palpitations), muscle and joint pain, constipation, flatulence and dyspepsia.

PREGNANCY AND LACTATION
Pregnancy: Pregnancy Category X. Atorvastatin is contraindicated in women who are pregnant or may become pregnant. Atorvastatin may cause fetal harm when administered to a pregnant woman. It should be administered to women of childbearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards.

Nursing Mothers: It is not known whether Amlodipine is excreted in human milk. It is not known whether Atorvastatin excreted in human milk, but a small amount of another drug in this class does pass into breast milk. Women taking this medicine, which includes Atorvastatin, should be advised not to nurse their infants.

DRUG INTERACTION
It can potentially interact with several other medications. Some of the medicines that may lead to this drug interactions include: antacids, oral contraceptives, certain antibiotics or anti-fungals, filtrates, grapefruit juice, niacin, protease inhibitors, rifampin, digoxin and spironolactone.

PACKAGING
ATV Plus tablet: Each box contains 3x10's tablets in alu-alu blister pack. Each film-coated tablet contains Atorvastatin Calcium INN equivalent to 10 mg Atorvastatin and Amlodipine Besilate BP equivalent to 5 mg Amlodipine.

PHARMACEUTICAL PRECAUTION
Store at 25°C (77°F); Store in a cool and dry place. Protect from light and heat.

WARNING
Keep out of the reach of children.

DELTA
Manufactured by
Delta Pharma Limited
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