



Am-Descol

(Amlodipine and Atorvastatin Tablets USP)

Tablets **5/10**
5/20
10/10
10/20

COMPOSITION:

Am-Descol 5/10 Tablets:

Each film coated tablet contains:

Amlodipine 5mg as Amlodipine Besylate USP.

Atorvastatin ... 10mg as Atorvastatin Calcium Trihydrate USP.

Am-Descol 5/20 Tablets:

Each film coated tablet contains:

Each film coated tablet contains:

Amlodipine 5mg as Amlodipine Besylate USP.

Atorvastatin ... 20mg as Atorvastatin Calcium Trihydrate USP.

Am-Descol 10/10 Tablets:

Each film coated tablet contains:

Amlodipine 10mg as Amlodipine Besylate USP.

Atorvastatin ... 10mg as Atorvastatin Calcium Trihydrate USP.

Am-Descol 10/20 Tablets:

Each film coated tablet contains:

Amlodipine 10mg as Amlodipine Besylate USP.

Atorvastatin ... 20mg as Atorvastatin Calcium Trihydrate USP.

USP Specs.

DESCRIPTION: **Am-Descol** (Amlodipine and Atorvastatin) tablets is a combination of the long acting calcium channel blocker Amlodipine Besylate with the synthetic lipid lowering agent Atorvastatin Calcium.

MECHANISM OF ACTION: **Am-Descol**, is a combination of two drugs, a dihydropyridine calcium antagonist (calcium ion antagonist or slow channel blocker) Amlodipine and an HMG-CoA reductase inhibitor Atorvastatin. The Amlodipine component of **Am-Descol** inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The Atorvastatin component of **Am-Descol** is a selective, competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol.

INDICATIONS AND USAGE: **Am-Descol** (Amlodipine and Atorvastatin) is indicated in patients for whom treatment with both (Amlodipine and Atorvastatin) is appropriate. **Am-Descol** is indicated to reduce the risk of fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke and to reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery disease. Amlodipine is indicated for the treatment of hypertension, chronic stable angina & vasospastic angina (Prinzmetal's or variant Angina). It may be used alone or in combination with other antihypertensive or antianginal agents. The Atorvastatin component is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-Cholesterol, apolipoprotein B, and triglycerides and to increase HDL-Cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb) elevated serum triglyceride levels (Fredrickson type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is indicated in patients without clinically evident cardiovascular disease, and with or without dyslipidemia, but with multiple risk factors for coronary heart disease such as smoking, hypertension, diabetes, low HDL-C, or a family history of early coronary heart disease.

DOSAGE: Dosage of **Am-Descol** must be individualized on the basis of both effectiveness and tolerance for each individual component in the treatment of hypertension/angina and hyperlipidemia. The dosage range for Amlodipine/Atorvastatin is 5mg/10mg to a maximum dose of 10mg/80mg once daily. The starting dose and maintenance dose should be individualized on the basis of both effectiveness and tolerance for each individual component in the treatment of hypertension/ angina and dyslipidemia. Doses may be taken at any time of day with or without food.

CONTRA-INDICATIONS: **Am-Descol** contains Atorvastatin and is therefore contra-indicated in patients with active liver disease or unexplained persistent elevations of serum transaminases. **Am-Descol** is contra-indicated in patients with known hypersensitivity to any component of this medication.

Pregnancy and Lactation: Amlodipine Besylate and Atorvastatin Calcium tablets are contra-indicated during pregnancy and in nursing mothers.

WARNINGS: Increased Angina and/or Myocardial Infarction: Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated.

Liver Dysfunction: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Liver function tests should be performed before the initiation of treatment and periodically thereafter. Patients who develop increased transaminase levels should be monitored until the abnormality(ies) resolve(s). An increase in ALT or AST of greater than three times the upper limit of normal persist, reduction of dose or withdrawal of Amlodipine/Atorvastatin is recommended.

Skeletal Muscle: Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with the Atorvastatin component of **Am-Descol** and with other drugs in the HMG-CoA reductase inhibitor class. Uncomplicated myalgia has been reported in atorvastatin-treated patients. Myopathy, defined as muscle aches or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values >10 times

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ULN, should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Am-Descol** therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

PRECAUTIONS: General: Since the vasodilation induced by the Amlodipine component of **Am-Descol** is gradual in onset, acute hypotension has rarely been reported after oral administration of Amlodipine. Nonetheless, caution should be exercised when administering **Am-Descol** as with any other peripheral vasodilator particularly in patients with severe aortic stenosis. Before instituting therapy with **Am-Descol**, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients. Calcium channel blockers should be used with caution in patients with heart failure. Caution should be exercised if an HMG-CoA reductase inhibitor is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

ADVERSE REACTIONS: The Amlodipine Component of Am-Descol: The most common side effects are headache and edema. Cardiovascular: arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, postural dizziness, postural hypotension, vasculitis. Central and Peripheral Nervous System: hypoaesthesia, neuropathy peripheral, paresthesia, tremor, vertigo. Gastrointestinal: anorexia, constipation, dyspepsia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia. General: allergic reaction, asthenia, hot flushes, malaise, pain, rigors, weight gain, weight decrease. Musculoskeletal System: arthralgia, arthrosis, muscle cramps. Psychiatric: sexual dysfunction (male), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization. Respiratory System: dyspnea. Skin and Appendages: angioedema, erythema multi-forme, pruritus, rash maculopapular. Special Senses: abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus. Urinary System: micturition frequency, micturition disorder, nocturia. Autonomic Nervous System: dry mouth, sweating increased. Metabolic and Nutritional: hyperglycemia, thirst, Hemopoietic: leukopenia, purpura, thrombocytopenia.

The Atorvastatin Component of Am-Descol: Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and transient. The most frequent adverse events thought to be related to Atorvastatin Calcium were constipation, flatulence, dyspepsia, abdominal pain, chest pain, nausea, bronchitis, rhinitis, insomnia, dizziness, arthritis and urinary tract infection.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:

Am-Descol 5/10 & 5/20 tablets are available in Alu Alu blister packs of 7'sx1. and 7'sx2. **Am-Descol** 10/10 & 10/20 tablets are available in Alu Alu blister pack of 7'sx2.



ایز اوٹر کی: ہر قلم کوڈ کوئی میں ایملو ڈیپین ۵ ملی گرام یا ۱۰ ملی گرام بحیثیت ایملو ڈیپین ٹیبلٹ اور ایملو ڈیپین ۱۰ ملی گرام یا ۲۰ ملی گرام (ایملو ایملو ڈیپین ٹیبلٹس) موجود ہے۔

عامت اور استعمال: **ایم۔ ڈیسکول** دو دواؤں (Amlodipine/Atorvastatin) کا مرکب ہے یہ ان مریضوں کو تجویز کی جاتی ہیں جن کے علاج کیلئے یہ دوا نہیں موزوں ہوں۔ **ایم۔ ڈیسکول** کوئی کا جز ایملو ڈیپین بلڈ فٹائرون میں فائو منڈ میں ایملو ڈیپین ایجنٹ کے مریضوں میں آٹھٹی عروقی سازی کے خطرے کو کم کرتی ہے جبکہ ایملو ڈیپین جسم میں موجود لیپو پروٹین اور Lipoprotein کو کم کرتا ہے ایملو ڈیپین کی خصوصیت ہے کہ یہ پیکر میں موجود انزائم HMG-CoA reductase اور Cholesterol synthesis کو روکتا ہے اور Hepatic LDL Receptors کی تعداد میں اضافہ کرتا ہے اور نتیجتاً LDL کے تخام میں تیزی آ جاتی ہے۔

خوراک اور طریقہ استعمال: بالغ افراد: تجویز کردہ خوراک کے استعمال سے پہلے مریضیں کو معیاری اور کو لیٹروں سے پاک محفوظ غذا کا استعمال کرائیں۔ **ایم۔ ڈیسکول** کے استعمال کے دوران معیاری غذا کا استعمال جاری رکھیں۔ ایملو ڈیپین کی ابتدائی خوراک ۵ ملی گرام روزانہ ہے جو کہ زیادہ سے زیادہ ۱۰ ملی گرام روزانہ تک بڑھائی جاسکتی ہے۔ جبکہ ایملو ڈیپین کی تجویز کردہ ابتدائی خوراک ۱۰ ملی گرام دن میں ایک مرتبہ۔ یہ خوراک معالج کے مشورے سے ۸۰ ملی گرام دن میں ایک مرتبہ تک بڑھائی جاسکتی ہے۔

ممنوعات: جن مریضوں کو ایملو ڈیپین یا ایملو ڈیپین یا دوا میں شامل دیگر اجزاء سے حساسیت ہو یا دوسری جگہ سے تعلق رکھنے والی بیماریوں میں مبتلا ہوں ان میں **ایم۔ ڈیسکول** کا استعمال منع ہے۔

مضرات: ایملو ڈیپین ایملو ڈیپین سے ہونے والے ممکنہ اثرات میں قبض، ہیپٹ میں درد، سردرد، تھکی، اسہال، نیند کی کمی، Dyspepsia, Flatulence اور Myalgia۔ **ایم۔ ڈیسکول** ہوتا، پیشاب کا بار بار آنا اور قدرتی دھیرہ شامل ہیں۔

احتیاط: **ایم۔ ڈیسکول** کے استعمال سے پہلے Liver Function Tests نہایت ضروری ہیں ایسے مریض جن میں ALT اور AST تارل سے زیادہ ہوں ان میں اس دوا کا استعمال نہ کریں۔ حالت زنجی اور دودھ پلانے والی ماؤں میں ڈاکٹر کے مشورے کے بغیر **ایم۔ ڈیسکول** استعمال نہ کریں۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: **ایم۔ ڈیسکول** 5/10 اور 5/20 7's x 1 اور 7's x 2 گولیوں کے ایملو ایملو ٹیبلٹس ایک میں دستیاب ہے۔

ایم۔ ڈیسکول 10/10 اور 10/20 7's x 2 گولیوں کے ایملو ایملو ٹیبلٹس ایک میں دستیاب ہے۔



Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.

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