

Amlodipine Besylates Cas No. : 111470-99-6

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Active Pharmaceuticals Ingredients Manufacturers



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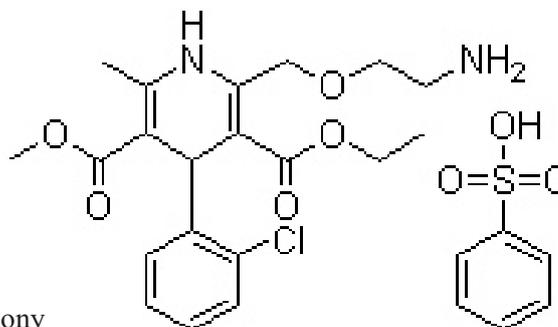
Taj Pharmaceuticals Ltd.

Amlodipine Besylates

CAS No. : 111470-99-6

**Chemical Structure :**amoldipine desylate Formula : C₂₀H₂₅CIN₂O₅.C₆H₆O₃S**Identification**

Synonyms Amlodipine besilate; 2-[(2-Aminoethoxy)methyl]-4-(2-chlorophenyl)-3-ethoxycarbonyl-5-methoxycarbonyl-1,4-dihydro-1,4-dihydropyridine benzenesulfonate.



Molecular Formula : C₂₀H₂₅CIN₂O₅.C₆H₆O₃S Molecular Weight 567.05 CAS Registry Number 111470-99-6.

Amlodipine Besylates Description

Amlodipine besylate is the besylate salt of amlodipine, a long-acting calcium channel blocker.

Amlodipine besylate is chemically described as 3-Ethyl-5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulphonate. Its molecular formula is C₂₀ H₂₅ CIN₂ O₅ · C₆ H₆ O₃ S, and its structural formula is:

Amlodipine besylate is a white crystalline powder with a molecular weight of 567.1. It is slightly soluble in water and sparingly soluble in ethanol. Amlodipine besylate tablets are formulated as white tablets equivalent to 2.5, 5 and 10 mg of amlodipine for oral administration. In addition to the active ingredient, amlodipine besylate, each tablet contains the following inactive ingredients: colloidal silicon dioxide, dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and stearic acid.

Amlodipine Besylate Precautions.**General**

Since the vasodilation induced by amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering amlodipine, particularly in patients with severe aortic stenosis.

USES

Amlodipine is approved to treat high blood pressure and heart disease. This eMedTV segment discusses these and other amlodipine uses, including "off-label" uses of the drug, such as when the drug is used as a treatment for migraines.

The fatigue is getting old. During the first six weeks after starting chemo I had fatigue in short bursts during the first few days after a treatment. The accumulation of chemo seems to be taking its toll however. I haven't been able to overcome fatigue the past two and a half weeks. After sleeping seven hours I can sleep another two a few hours later. Its obvious the additional rest is necessary because insomnia is now a thing of the past.



Taj Pharmaceuticals.Ltd
Amlodipine Besylate
CAS 111470-99-6

avoid drinking alcohol while taking amlodipine. Alcohol can further lower your blood pressure and may increase some of the side effects of amlodipine.

If you are being treated for high blood pressure, keep using this medication even if you feel fine. You may need to use blood pressure medication for the rest of your life.

Amlodipine is only part of a complete program of treatment that may also include diet, exercise, weight control, and other medications. Follow your diet, medication, and exercise routines very closely.

Tell your doctor about all other heart or blood pressure medications you are taking.

Your chest pain may become worse when you first start taking amlodipine or when your dose is increased. Call your doctor if your chest pain is severe or ongoing.

Amlodipine slows the movement of calcium through muscle cells in the walls of blood vessels. Calcium is required for these muscle cells to contract, thus amlodipine causes the muscle cells to relax. This causes the blood vessels to dilate.

Blood pressure depends on the force with which the heart pumps the blood, and on the diameter of blood vessels and the volume of blood in circulation. Blood pressure increases if the blood vessels are narrow or if the volume is high. Dilating the blood vessels in the extremities therefore decreases blood pressure.

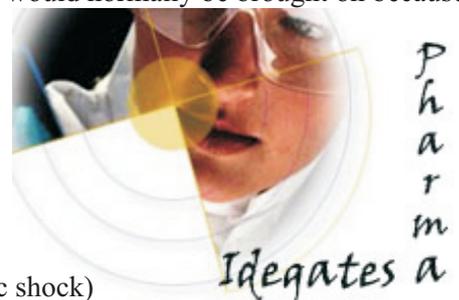
The coronary arteries in the heart are also dilated by amlodipine, and this allows more blood, and therefore oxygen, to be delivered to the heart at any time. Overall the heart is required to use less effort to pump blood around the body, and is also given a greater oxygen supply. This prevents the pain of angina, which would normally be brought on because of a lack of oxygen supply to the heart.

Not to be used in

- * Allergy to related calcium channel blockers (dihydropyridines)
- * Angina not well controlled by medical treatment (unstable angina)
- * Breastfeeding
- * Failure of the heart to maintain adequate circulation of blood (cardiogenic shock)
- * Narrowing of the main artery coming from the heart (aortic stenosis)
- * Pregnancy

This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such an allergy.

If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.





SIDE EFFECTS

with any medicine, there are possible side effects with amlodipine besylate (Norvasc®); however, not everyone who takes amlodipine will experience side effects. In fact, most people tolerate amlodipine well. When side effects do occur, in most cases they are minor and either require no treatment or can be easily treated by you or your healthcare provider.

(This article covers many, but not all, possible side effects with amlodipine. Your healthcare provider can discuss a more complete list of amlodipine side effects with you.)

Common Amlodipine Side Effects

Amlodipine has been studied thoroughly in clinical trials in which a group of people taking the drug have side effects documented and compared to another group not taking the medicine.

This way, it is possible to see what side effects occur, how often they appear, and how they compare to the group not taking the medicine.

How to take amlodipine

Always read the manufacturer's information leaflet, if possible before beginning treatment.

Take amlodipine exactly as directed by your doctor.

Swallow amlodipine whole with a glass of water.

Try to take amlodipine at the same times each day to avoid missing any doses.

If you miss a dose of amlodipine take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and continue taking it at the usual times. Never take two doses at the same time.

Do not stop taking amlodipine without speaking to your doctor first.

Amlodipine is for you. Never give it to others, even if their condition appears to be the same as yours.

Never take more than the prescribed dose. If you suspect that you or someone else has taken an overdose of this preparation contact your doctor or go to the accident and emergency department of your local hospital. Where possible take the container with you, even if it is empty.

There are other possible amlodipine side effects that can occur. These rare amlodipine side effects occur in less than 1 percent of people. For these side effects, it is difficult to tell whether the side effect is actually caused by the amlodipine medicine or something else.

DOSAGE

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

The usual initial antihypertensive oral dose of amlodipine is 5 mg once daily with a maximum dose of 10 mg once daily. Small, fragile, or elderly individuals, or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding amlodipine to other antihypertensive therapy.

Dosage should be adjusted according to each patient's need. In general, titration should proceed over 7 to 14 days so that the physician can fully assess the patient's response to each dose level. Titration may proceed more rapidly, however, if clinically warranted, provided the patient is assessed frequently.

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. Most patients will require 10 mg for adequate effect. See ADVERSE REACTIONS section for information related to dosage and side effects.



Amlodipine Besylates may be substituted for its individually titrated components. Patients may be given the equivalent dose of Amlodipine Besylates or a dose of Amlodipine Besylates with increased amounts of amlodipine, atorvastatin or both for additional antianginal effects, blood pressure lowering, or lipid lowering effect.

How should you take Amlodipine besylate?

You should take Amlodipine besylate exactly as prescribed, even if your symptoms have disappeared. You will begin to see a drop in your blood pressure 24 hours after you start the medication.

*** If you miss a dose...**

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Never take 2 doses at the same time.

*** Storage instructions...**

Store at room temperature in a tightly closed container, away from light.

Why is Amlodipine besylate prescribed?

Norvasc is prescribed for angina, a condition characterized by episodes of crushing chest pain that usually results from a lack of oxygen in the heart muscle due to clogged arteries. Norvasc is also prescribed for high blood pressure. It is a type of medication called a calcium channel blocker. These drugs dilate blood vessels and slow the heart to reduce blood pressure and the pain of angina.

Interactions with Foods and Other Compounds

Grapefruit juice

Ingestion of grapefruit juice has been shown to increase the absorption of felodipine (a drug similar in structure and action to that of amlodipine) and to increase the adverse effects of the medication in patients with hypertension. Until more is known, it seems that grapefruit juice should not be ingested by people taking amlodipine or similar drugs.³ The same effects might be seen from eating grapefruit as from drinking its juice.

Pomegranate juice

Pomegranate juice has been shown to inhibit the same enzyme that is inhibited by grapefruit juice.^{4 5} The degree of inhibition is about the same for each of these juices. Therefore, it would be reasonable to expect that pomegranate juice might interact with amlodipine in the same way that grapefruit juice does.

Note: Veterinary use

There have been anecdotal reports of oseltamivir reducing disease severity and hospitalization time in canine parvovirus infection. The drug may limit the ability of the virus to invade the crypt cells of the small intestine and decrease gastrointestinal bacteria colonization and toxin production.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:

91 022 30601000.

This leaflet was prepared by
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