

Stadovas 5mg Tablet

Stadovas 10mg Tablet

(Amlodipine besilate)

Consumer Medication Information Leaflet (RiMUP)

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What Stadovas is used for

Stadovas tablet contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists. Your medicine is used alone or in combination with other classes of antihypertension agents (agents used to treat high blood pressure) in the management of hypertension or with other antianginal agents (agents used to treat chest pain) in the management of Prinzmetal variant angina and chronic stable angina pectoris.

How Stadovas works

In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, Stadovas works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Your medicine does not provide immediate relief of chest pain caused by angina.

Before you take Stadovas

When you must not use it

You are allergic (hypersensitive) to amlodipine, or any of the other ingredients of your medicine, or to any other calcium antagonists.

You have cardiogenic shock, suffered a myocardial infarction in the previous 2 to 4 weeks, or in acute unstable angina, in treatment an angina attack in chronic stable angina.

You are pregnant or lactation.

Before you start to use it

Stadovas can be taken without regard to meals.

Taking other medicine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

How to take Stadovas

How much to use

Adults: Starting dose for high blood pressure and angina: 5 mg once a day. Depend on the individual patient's response, the dosage may be increased to a maximum dose of 10 mg.

For children, safety and effectiveness of amlodipine have not been established.

When to use it

Taking your medicine at the same time each day is mostly recommended.

How long to use it

Your doctor will advise you how long to take your medicine. It is important to keep taking the tablets.

If you forget to use it

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a missed dose.

If you use too much (overdose)

If you or someone else has taken too much amlodipine, contact your doctor or pharmacist immediately.

Symptoms of overdose are excessive peripheral vasodilation (dilation of the veins and arteries of the periphery) with marked hypotension (low blood pressure) and possibly a reflex tachycardia (increased heart rate in response to some stimulus conveyed through the cardiac nerves). Active cardiac and respiratory monitoring should be instituted. Blood pressure should be monitored more frequently than usual. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (drugs that increase blood pressure such as phenylephrine) should be considered with attention to circulating volume and urine output.

Intravenous calcium gluconate may help to reverse the effects of calcium entry blockade. As amlodipine is highly protein bound, hemodialysis (most common method used to treat advanced and permanent kidney failure) is not likely to be of benefit.

While you are using Stadovas

Things you must do

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

You always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

Things you must not do

Stop the treatment earlier than agreed without discussing this with your doctor or pharmacist. Your condition may return if you stop using your medicine before you are advised.

Things to be careful of

You should inform your doctor if you have or have had any of the following conditions:

Recent heart attack (within the last month), heart failure. Hepatic impairment.

There is no special dosage for the elderly; however, care must be taken when the dose is increased.

Side effects

The most common adverse effects of amlodipine are associated with its vasodilator action (widening of the blood vessels) and often diminish on continued therapy. They include dizziness, flushing, headache, hypotension, peripheral oedema (swelling of the ankles, feet or fingers), tachycardia (faster heart beat), and palpitations (a noticeably rapid, strong, or irregular heartbeat). Nausea (feeling sick) and other gastrointestinal disturbances, increased micturition (periodic discharge of urine from the bladder through the urethra) frequency, lethargy (mental and physical sluggishness), eye pain, visual disturbances, and mental depression have also occurred.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Stadovas

Storage

Keep out of reach of children.

Protect from light Do not store above 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

- Stadovas 5: White to off-white, oval-shaped tablet, biconvex, engraved “5” on one side and plain on the other side.
- Stadovas 10: White to off-white, round-shaped tablet, flat, engraved “STADOVAS 10” on one side and fracture line on the other side.

Ingredients

- Active ingredients:
Stadovas 5: Amlodipine (as besilate) 5 mg.
Stadovas 10: Amlodipine (as besilate) 10 mg.
- Inactive ingredients are maize starch, mannitol, pregelatinised maize starch, stearic acid and colloidal anhydrous silica.

MAL number:

Stadovas 5: MAL13115203AZ

Stadovas 10: MAL13115204AZ

Manufacturer

STELLAPHARM J.V. CO., LTD. –
BRANCH 1 (A Joint Venture Company of Auxilto GmbH, Germany)
No. 40 Tu Do Avenue, Vietnam -
Singapore Industrial Park, An Phu Ward,
Thuan An Town, Binh Duong Province,
Vietnam.

Product Registration Holder

STADPHARM SDN. BHD.
E-9-01, Oasis Square, Ara Damansara No:
2, Jalan PJU 1A/7A, 47301 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

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