Amlodipine besylate is a type of medicine known as a calcium channel blocker. It works by relaxing the muscles of the heart and blood vessels, which lets your blood flow more easily and helps lower your blood pressure. Drugs that lower blood pressure can help prevent heart attacks and strokes, which are serious conditions.

Amlodipine besylate tablets are taken by mouth. They are available as white to off white round tablets with “128” debossed on one side and “C” on other side.

### Dosage and Administration

- **Adults:**
  - The usual initial antihypertensive oral dose of amlodipine besylate tablet is 5 mg once daily, and the maximum dose is 10 mg daily.
  - Titrate slowly in patients with severe hypertension.

- **Elderly Patients:**
  - The elderly may require a lower starting dose (5 mg once daily) or a slower titration to a higher dose because of the greater risk of hypotension and other adverse reactions in the elderly.

- **Renal Impairment:**
  - Patients with impaired renal function (creatinine clearance ≤ 30 mL/min) may be more sensitive to the effects of amlodipine besylate. The recommended dose for patients with mild to moderate renal insufficiency is 5 mg once daily.

### Contraindications

- Amlodipine besylate is contraindicated in patients with a known hypersensitivity to amlodipine or any of its ingredients.

### Precautions

- Patients should be advised to avoid driving or engaging in other activities requiring alertness until their response to amlodipine besylate tablets is known.

### Adverse Reactions

- The most common side effects of amlodipine besylate tablets include edema, peripheral edema, and leg cramps.

### Drug Interactions

- Amlodipine besylate tablets should be used with caution in patients receiving other drugs that lower blood pressure, such as beta blockers, ACE inhibitors, and angiotensin II receptor blockers.

### Special Populations

- The safety and efficacy of amlodipine besylate tablets in pregnant or breastfeeding women have not been established.

### Full Prescribing Information

- Detailed information on the use, precautions, and adverse effects of amlodipine besylate tablets can be found in the full prescribing information available from the manufacturer.

### Patient Information

- Amlodipine besylate tablets should be stored at room temperature and kept out of reach of children.

### Notes

- The prescribing information and patient information for amlodipine besylate tablets can be obtained from the manufacturer's website or by contacting the manufacturer directly.
While you are taking amlodipine besylate tablets, do not stop taking your other prescription medicines, including any other blood pressure medicines, without talking to your doctor first. If you take too much amlodipine besylate tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

What should I avoid while taking amlodipine besylate tablets? Do not start any new prescription or non-prescription medicines, including dietary supplements, unless you check with your doctor first.

• Do not drive or operate dangerous machinery if you get dizziness or light-headedness
• Do not drink alcohol or take other medicines that may slow your central nervous system (such as sedatives, tranquilizers, sleep aids, or cold medicines) without talking to your doctor first
• What are the possible side effects of amlodipine besylate tablets?

An overview of the possible side effects that have been reported with amlodipine besylate tablets is provided. These side effects may occur during the first few weeks of treatment with amlodipine besylate tablets or may occur at any time during treatment.

- Sedative effects: When you first start taking amlodipine besylate tablets, you may have tiredness, headache, dizziness, or light-headedness. To avoid falls, make sure you are able to perform ordinary activities before you get out of bed. You may need to lower your dose, or stop treatment and then start again at a lower dose. These side effects usually go away as your body gets used to the medicine. Call your doctor if they continue or become troublesome.
- Nervous system effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Headache
  - Nervousness
  - Numbness or tingling in your hands, feet, or lips
  - Memory problems
  - Heart palpitations (very fast heartbeat)
- GI effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Nausea
  - Vomiting
  - Diarrhea
  - Constipation
  - Stomach pain
- Respiratory effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Cough
  - Sneezing
  - Wheezing
  - Colds
  - Flu
- Renal effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Urinary retention
- Skin and muscle effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Rash
  - Itching
- Other effects: Call your doctor if you experience any of the following side effects while you are taking amlodipine besylate tablets:
  - Influenza-like symptoms (fever, chills, body aches, cough, or sore throat)
  - Headache

The most common side effects associated with amlodipine besylate tablets are:

- General: Fatigue, edema, cold intolerance
- GI: Upper respiratory respiratory: Rhinitis, cough
- Respiratory: Cough
- Musculoskeletal: Myalgia, arthralgia

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How do I store amlodipine besylate tablets?

Store at 20°C to 25°C (68°F to 77°F). [See USP controlled room temperature (20°C to 25°C)].

How should I store amlodipine besylate tablets?

Do not store near heat sources. Do not use near open flames. Do not store in areas where temperatures are too high or too low. Do not spill amlodipine besylate tablets on your skin. Do not dispose of any unneeded amlodipine besylate tablets by pouring them down the drain or flushing them down the toilet. Do not flush amlodipine besylate tablets down a toilet.

Perforation

After oral administration of therapeutic doses of amlodipine besylate, absorption produces peak plasma concentrations at 2.5-6 hours. Amlodipine besylate tablets rapidly achieve steady state conditions in the body within a few days. Amlodipine besylate tablets are metabolized by the liver and the primary route of elimination is unchanged drug. The elimination half-life of amlodipine besylate tablets is 30-40 hours.

Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the movement of calcium ions across the cardiac and smooth muscle cell membranes. This inhibitory action results in the relaxation of vascular smooth muscle and a reduction in peripheral vascular resistance. Amlodipine besylate tablets are a white or almost white powder with a molecular weight of 567.1. It is slightly soluble in water and methylene chloride.

Amlodipine besylate is used to treat high blood pressure in adults. It is taken by mouth. Amlodipine besylate tablets are available in 2.5 mg, 5 mg, and 10 mg tablets. Amlodipine besylate tablets are available in two strengths: 2.5 mg and 5 mg. Amlodipine besylate tablets are used to treat high blood pressure in adults.

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