

Package leaflet: Information for the patient

AMOSARC 10 (Amlodipine Besilate Tablets 10 mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What AMOSARC 10 is and what it is used for
2. What you need to know before you take AMOSARC 10
3. How to take AMOSARC 10
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1. What AMOSARC 10 is and what it is used for

Amorarc 10 belongs to a group of medicines called calcium antagonists.

Amorarc 10 are used to treat:

- high blood pressure (hypertension)
- chest pain due to narrowing of the blood vessels of the heart muscle (angina pectoris) or the more rare form of chest pain caused by cramping of the blood vessels of the heart muscle called Prinzmetal or variant angina.

If you suffer from high blood pressure, Amlodipine works by relaxing blood vessels, so that blood passes through them more easily.

If you suffer from angina, Amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Amlodipine does not provide immediate relief of chest pain from angina.

2. What you need to know before you take AMOSARC 10

Do not take Amorarc 10, if you

- are allergic (hypersensitive) to amlodipine or any of the other ingredients of this medicine listed, or to any other calcium antagonists (the so-called dihydropyridine derivatives like felodipine, nifedipine, nimodipine). This may be itching, reddening of the skin or difficulty in breathing.
- are suffering from cardiogenic shock. This is a condition where the heart is unable to pump sufficient blood around the body. The symptoms of cardiogenic shock are low blood pressure, low pulse and fast heartbeat.

- are suffering from narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body) or if you suffer from heart failure after a heart attack.
- suffer from chest pain at rest or with minimal effort (unstable angina pectoris).
- are pregnant or breast-feeding.
- have severe low blood pressure (hypotension).

Warnings and precautions

Before taking Amorarc 10, tell your doctor if you

- have heart failure or have suffered a heart attack during the past month.
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- have liver problems
- are giving this medicine to a child under 18 years of age
- are elderly, your doctor may monitor you closely.

Children and adolescents

Amlodipine has not been studied in children under the age of 6 years. Amlodipine should only be used for hypertension in children and adolescents from 6 years to 17 years of age.

For more information, talk to your doctor.

Other medicines and Amorarc 10

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

Some medicines (including medicines obtained without prescription, herbal medications or natural products) may interact with Amlodipine. This means that the action of both medicines can be changed.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines that can lower blood pressure (e.g. verapamil, diltiazem)
- Ketoconazole and itraconazole (antifungal medicines used to treat skin and fungal infections)
- HIV-protease-inhibitors (antiviral medicines used to treat HIV infections, e.g. ritonavir)
- Clarithromycin, erythromycin and telithromycin, rifampicin, rifabutin (antibiotics)
- Nefazodone (medicine to treat depression)
- St. John's wort (*Hypericum perforatum*; herbal medicine for depression)
- Dexamethasone (corticosteroid used to treat inflammatory and autoimmune conditions such as rheumatoid arthritis)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (medicine used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

- Phenobarbital, phenytoin and carbamazepin (medicines for epilepsy)
- Ritonavir, Indinavir, Nelfinavir, Nevirapine (antiviral medicine used to treat HIV and AIDS)
- Sildenafil (medicine for impotence)

Amorarc 10 may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Taking Amorarc 10 with food and drink

Amorarc 10 should be taken with a glass of liquid (e.g. a glass of water) with or without food.

Grapefruit juice and grapefruit should not be consumed by people who are taking Amorarc 10. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient Amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine.

Pregnancy and breast-feeding

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Amorarc 10.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or about to start breast-feeding you must tell your doctor before taking Amlodipine tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Amorarc 10 may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Such side effects are more likely to occur at the start of treatment or following an increase in dose. If you suffer from these effects, you should not drive or perform other activities that require you to be alert.

3. How to take AMOSARC 10

Dosage

Always take Amorarc 10 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Methods and routes of administration

This medicine can be used before or after food and drinks. You should take this medicine at the same time each day with a drink of water. Do not take Amlodipine with grapefruit juice.

Adults

The usual starting dose is 5 mg once daily. If necessary, your doctor may increase the dose to 10 mg once daily.

Use in children and adolescents (6 -17 years old)

The recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.

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

Elderly patients

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

If you have kidney problems

The normal dosage is recommended. Amlodipine cannot be removed from the blood by dialysis (artificial kidney). Amorarc 10 should be administered with particular caution to patients undergoing dialysis.

If you have liver problems

Your doctor will decide if this medicine is suitable for you and the correct dose for you to take.

If you take more Amorarc 10 than you should

If you or someone else has taken too much Amlodipine, contact your nearest hospital casualty department. Please carry with you the product leaflet or remaining tablets for better identification of the doctor. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions, for example). Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed, faint or weak, problems with breathing, having to urinate very often. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

If you forget to take Amorarc 10

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amorarc 10

Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Amorarac 10 can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) toxic epidermal necrolysis or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following very common side effect has been reported. If this causes you problems or if it lasts for more than one week, you should contact your doctor.

Very common (may affect more than 1 in 10 people)

- Oedema (fluid retention)

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

Common (may affect up to 1 in 10 people)

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion,
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Swollen ankles

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon (may affect up to 1 in 100 people)

- Enlarged breasts or discomfort in men
- Sleep disorders, irritability, depression
- Pain, feeling unwell, dry mouth, uncontrolled shaking, pins and needles, increased sweating
- Problems with your eye-sight (visual disturbances)
- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities
- Numbness or tingling sensation in your limbs, loss of pain sensation

- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Ringing or buzzing in the ears
- Fainting, increased heart rate, chest pain, aggravation of angina may occur at the beginning of the treatment
- Low blood pressure, inflammation of the blood vessels
- Breathing difficulties, inflammation of the nasal mucosa, cough
- Dry mouth, vomiting (being sick), diarrhoea, constipation, swollen gums
- Prickling and tingling sensation of the skin , itching, red patches on skin, nettle rash, hair loss, discolouration of the skin
- Muscle cramps, back pain, muscle and joint pain
- Increased need to urinate
- Impotence,
- Increase or decrease in weight

Rare (may affect up to 1 in 1,000 people)

- Confusion

Very rare (may affect up to 1 in 10,000 people)

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more Information on the safety of this medicine.

5. How to store AMOSARC 10

Store at temperatures not exceeding 30°C. Protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What AMOSARC 10 contains –

-The active substance is Amlodipine Besilate BP

Each Uncoated contains: Amlodipine Besilate BP Eq. to Amlodipine10 mg

- The other ingredients are Microcrystalline Cellulose, PVPK-30, Purified Water, Magnesium Stearate, Sodium Starch Glycolate

What AMOSARC 10 looks like and contents of the pack

AMOSARC 10 is White colored octagonal shaped uncoated tablets having a breakline on one side and other side plain.

AMOSARC 10 is available in blisters 10 tablets. Each blister pack contains 10 tablets. 3 blisters are packed in a carton.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

MVC Pharmaceuticals

Shop No.1Ground Floor,

Parasmani Apt., Daheli.Bhilad,

Tal-Umergam, Dist.-Valsad-396105

Gujarat

Manufacturer:

MVC Pharmaceuticals

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