

Package leaflet: information for the user

Hipres 5 mg tablets

Hipres 10 mg tablets

Amlodipine

Read all of this leaflet carefully before you start using 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are similar to yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hipres is and what it is used for
2. What you need to know before you take Hipres
3. How to take Hipres
4. Possible side effects
5. How to store Hipres
6. Contents of the pack and other information

1. What Hipres is and what it is used for

Hipres contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Hipres is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina (and also its rare form called Prinzmetal's or variant angina).

In patients with high blood pressure, this medicine works by relaxing the blood vessel walls, so that blood could pass through the vessels more easily. In patients with angina, Hipres works by improving blood supply to the heart muscle, which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain caused by angina.

2. What you need to know before you take Hipres

Do not take Hipres

- If you are allergic to amlodipine or any of the other ingredients of this medicine (listed in section 6), or to any other calcium antagonists. Allergy symptoms may include itching, redness of the skin or difficulty breathing.
- If you have very low blood pressure (hypotension).
- If you have a narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (condition in which your heart is unable to pump enough blood into your body).
- You suffer from heart failure as a result of a heart attack.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hipres.

Tell your doctor if you have or have had any of the following conditions:

- Recent heart attack.
- Heart failure.
- Severe increase in blood pressure (hypertensive crisis).
- Liver disease.

- You are elderly and your dose needs to be increased.

Children and adolescents

Hipres has not been studied in children under 6 years of age. Hipres can only be used in children and adolescents with hypertension at the age of 6...17 (see section 3). For more information, ask your doctor.

Other medicines and Hipres

Hipres may affect or be affected by other medicines, such as:

- Ketoconazole, itraconazole (anti-fungal medicines).
- Ritonavir, indinavir, nelfinavir (so-called protease inhibitors used to treat HIV).
- Rifampicin, erythromycin, clarithromycin (antibiotics, which are used to treat bacterial infections).
- St. John's Wort (*Hypericum perforatum*).
- Verapamil, diltiazem (heart medicines).
- Dantrolene (infusion for severe body temperature abnormalities).
- Tacrolimus, sirolimus, temsirolimus and everolimus (medicine suppressing the activity of the immune system).
- Simvastatin (cholesterol lowering medicine).
- Cyclosporine (immunosuppressant).

Hipres may lower your blood pressure even further if you are already taking other medicines to treat your high blood pressure.

Hipres with food, drink, and alcohol

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

Pregnancy and breast-feeding

The safety of amlodipine in human pregnancy has not been established.

Small quantities of amlodipine are known to be excreted into breast milk. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Talk to your doctor or pharmacist before using any medicine.

Driving and using machines

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

Hipres contains sodium

This medicinal product contains less than 1 mmol (23 mg) sodium per tablet, ie essentially 'sodium-free'.

3. How to take Hipres

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose of Hipres is 5 mg once a day. The dose of Hipres may be increased to 10 mg once a day.

This medicine may be taken before or after eating or drinking. It is recommended to take the medicine with a glass of water at the same time every day. Do not take Hipres with grapefruit juice.

Use in children and adolescents

For children (ages 6...17), the recommended starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. The tablet can be divided into equal doses.

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

If you take more Hipres tablets than you should

Taking too many tablets may cause low or even dangerously low blood pressure. You may experience dizziness, vertigo, light-headedness or feelings of faintness. Severe lowering of blood pressure may lead to shock. In such cases, your skin may feel cool and clammy., loss of consciousness may also occur. Seek immediate medical attention if you take too many Hipres tablets.

If you forget to take Hipres

Do not worry. If you forget to take a tablet, skip 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 Hipres

Your doctor will tell you how long to take this medicine for. Your condition may return if you stop using the medicine before you are told to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor **immediately** if you get any of the following very rare but severe side effects after taking this medicine:

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing.
- Swelling of the eyelids, face or lips.
- Swelling of the tongue and throat, which may cause severe breathing difficulties;
- Severe skin reactions, including severe rash, hives, redness of the skin over the 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, arrhythmia.
- Pancreatitis which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these causes you problems **or lasts for more than one week, contact your doctor.**

Very common: may affect more than 1 in 10 people

- Swelling of the ankles (oedema).

Common: may affect up to 1 in 10 people

- Headache, dizziness, sleepiness (especially at the beginning of treatment).
- Palpitations, flushing.
- Abdominal pain, nausea.
- Changes in bowel habits, diarrhoea, constipation, indigestion.
- Tiredness, weakness.

- Visual disturbances, double vision.
- Muscle cramps.

Other known side effects are listed below. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

- Mood changes, anxiety, depression, insomnia.
- Trembling, taste abnormalities, fainting, weakness.
- Numbness or tingling sensation in your limbs, loss of pain sensation.
- Ringing in the ears.
- Low blood pressure.
- Sneezing / runny nose caused by inflammation of the nasal mucous membrane (rhinitis).
- Cough.
- Dry mouth, vomiting (feeling unwell).
- Hair loss, increased sweating, itchy skin, red patches on the skin, skin discolouration.
- Difficulty passing urine, increased need to urinate at night, increased frequency of urination.
- In men: inability to obtain an erection, discomfort or enlargement of the mammary glands.
- Pain, feeling unwell.
- Joint or muscle pain, back pain.
- Weight gain or loss.

Rare: may affect up to 1 in 1,000 people

- Confusion.

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

- Decreased white blood cell count, decrease in blood platelets, which may result in unusual bruising or easy bleeding (red blood cell damage),
- Increased blood sugar level (hyperglycemia).
- Nerve damage, which may 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), increase in liver enzyme activity, which may affect some medical tests.
- Increased muscle tension.
- Inflammation of blood vessels, often accompanied with skin rash.
- Sensitivity to light.
- Disorders combining rigidity, tremor, and/or movement disorders.

Unknown: incidence cannot be estimated from available data

- Trembling, rigidity, masklike face, slow movements and shuffling of the feet, unbalanced gait.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hipres

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

Do not store at a temperature higher than 30 °C, store in the original package and protect from moisture and light.

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

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 Hipres contains

- The active substance is amlodipine. Each tablet contains 5 mg or 10 mg of amlodipine (as maleate).
- The excipients are microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, colloidal anhydrous silicon dioxide and magnesium stearate.

What Hipres looks like and contents of the pack

Each pack contains 30, 60, or 90 tablets.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo Mesto
Šmarješka cesta 6
8501 Novo mesto
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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