

Package leaflet: information for the user

Amlodipine (as besylate) Accord 5 mg, tablets
Amlodipine (as besylate) Accord 10 mg, tablets
amlodipine

Read the entire 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.

Do not pass this medicine on to others. It may harm them, even if their symptoms 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.

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1. What is Amlodipine (as besylate) Accord and what is this medicine used for?

Amlodipine (as besylate) Accord contains the active substance amlodipine, which belongs to the group of medicines called calcium antagonists. are called.

Amlodipine (as besylate) Accord is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina pectoris; a rare form of this is Prinzmetal's angina or variant angina.

In patients with high blood pressure, this medicine works by relaxing the blood vessels, so that blood can flow more easily.

In patients with angina pectoris, Amlodipine (as besylate) Accord works by improving the blood supply to the heart muscle, which then receives more oxygen; as a result, chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina pectoris.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6. Or you are allergic to other calcium antagonists. The allergy may manifest as itching, reddening of the skin, or difficulty breathing.

You have very low blood pressure (hypotension).

You have a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to pump enough blood to the body).

You are suffering from heart failure after a heart attack.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. You should inform 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

If you are older and your dose needs to be increased.

Children and adolescents up to 18 years

Amlodipine (as besylate) besylate has not been studied in children under 6 years. Amlodipine (as besilate) Accord may only be used in children and adolescents aged 6 to 17 years with high blood pressure (hypertension) (see section 3). Consult your doctor for more information.

Are you using any other medicines?

Are you using Amlodipine (as besylate) Accord in addition to other medicines, have you recently done so or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Amlodipine (as besylate) Accord can affect or be affected by other medicines, such as:

Ketoconazole, itraconazole (antifungal agents)

ritonavir, indinavir, nelfinavir (so-called protease inhibitors used for the treatment of HIV)

rifampicin, erythromycin, clarithromycin (antibiotics)

hypericum perforatum (St. John's wort)

verapamil, diltiazem (cardiac drugs)

dantrolene (infusion for severe abnormalities in body temperature).

tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works)

simvastatin (cholesterol-lowering medicine)

cyclosporine (an immunosuppressant)

Amlodipine (as besylate) Accord may further lower your blood pressure if you are already using other medications for the treatment of your high blood pressure.

What should you pay attention to with food, drink, and alcohol?

You should not eat grapefruit or drink grapefruit juice if you are using Amlodipine (as besylate) Accord . Grapefruit and grapefruit juice can increase the levels of the active substance amlodipine in the blood, leading to an unpredictable increase in the blood pressure-lowering effect of Amlodipine (as besylate) Accord can arise.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medication.

Pregnancy

The safety of amlodipine during pregnancy in humans has not been established. If you think you might be pregnant or want to become pregnant, you should inform your doctor before using this medicine.

Breastfeeding

It has been shown that amlodipine passes into breast milk in small amounts. If you are breastfeeding or planning to start breastfeeding, you should tell your doctor before starting to use this medicine.

Ask your doctor or pharmacist for advice before using medications.

Driving ability and the use of machines

Amlodipine (as besylate) Accord may affect your ability to drive or operate machines. If you feel sick, dizzy, tired, or have a headache from the tablets, do not drive or operate machines and contact your doctor immediately.

Amlodipine (as besylate) Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Dosage

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended starting dose is 5 mg Amlodipine (as besylate) Accord once a day. The dose can be increased to Amlodipine (as besylate) Accord 10 mg once daily.

This medicine can be used before and after eating and drinking. You should take this medicine at the same time every day with some water. Do not take Amlodipine (as besylate) Accord with grapefruit juice.

Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg per day. The maximum recommended dose is 5 mg per day. Amlodipine 2.5 mg is currently not available and the dose of 2.5 mg cannot be obtained with Amlodipine (as besylate) Accord 5 mg, as these tablets are not manufactured to be broken into two equal halves.

It is important that you continue taking the tablets. Do not wait until your tablets are finished before going to your doctor.

Have you taken too much of this medicine?

If you have taken too many tablets, your blood pressure may drop to a low or even dangerously low level. You may feel dizzy, lightheaded, faint, or weak. If the blood pressure drops too much, shock may occur.

Excess fluid may accumulate in your lungs (pulmonary edema), which can cause shortness of breath that may occur 24-48 hours after ingestion.

Your skin may feel cool and clammy, and you may lose consciousness. Seek immediate medical attention if you have taken too much Amlodipine (as besylate) Accord have taken.

Have you forgotten to take this medicine?

Do not worry. If you have forgotten a tablet, skip that dose entirely. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Your doctor will advise you on how long to use this medicine. Your condition may return if you stop using this medicine earlier than advised.

Do you have any other questions about using this medicine? Then contact your doctor, pharmacist, or nurse.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them. See your doctor immediately if you experience any of the following side effects after taking this medicine.

Sudden wheezing, chest pain, shortness of breath, or breathing problems;

- Swollen eyelids, face, or lips;
- Swollen tongue and throat causing severe breathing difficulties;
- Swollen tongue and throat causing severe breathing difficulties;
- Severe skin reactions such as intense skin rash, hives, reddening of the skin over the entire 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 heartbeat;
- Inflammation of the pancreas that can lead to severe abdominal and back pain, making you feel very unwell.

The following very common side effect was reported. If you experience this side effect or if it persists for more than a week, contact your doctor.

Very common: may occur in more than 1 in 10 people

- Fluid retention in tissue (edema)

The following common side effects were reported. If you experience these side effects or if they persist for more than a week, contact your doctor.

Common: may occur in up to 1 in 10 people

- Headache, dizziness, drowsiness (especially at the start of treatment)
- Palpitations (being aware of your heartbeat), excessive flushing
- Abdominal pain, nausea
- Change in bowel habits, diarrhea, constipation, indigestion
- Fatigue, weakness
- Disorders of the vision, double vision
- Muscle cramps
- Swelling of the ankles

Other side effects that have been reported are listed below. Are you experiencing significant discomfort from any of these side effects? Or do you have a side effect that is not mentioned in this leaflet? Then contact your doctor or pharmacist.

Sometimes: may occur in up to 1 in 100 people

- Mood changes, feelings of anxiety, depression, insomnia
- Tremors, taste disturbances, fainting
- 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 inner lining of the nose (rhinitis)
- Coughing
- Dry mouth, vomiting (throwing up)
- Hair loss, increased sweating, itchy skin, red spots on the skin, skin discoloration
- Disturbed urination, increased urge to urinate at night, more frequent urination
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, feeling unwell Muscle or joint pain
- , back painWeight gain or
- weight loss Rare: may occur in up to 1 in 1,000 people Confusion

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

- Confusion

Increased blood sugar level (hyperglycemia)

- A nerve disorder that can cause muscle weakness, tingling, or numbness
- Increased blood sugar level (hyperglycemia)
- A disorder of the nerves that can cause muscle weakness, tingling, or numbness
- Swollen gums
- Swollen abdomen (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), increase in liver enzymes that may affect certain medical tests
- Increased muscle tension
- Inflammation of the blood vessels, often with a rash
- Sensitivity to light
- Combination of stiffness, tremors and/or movement disorders

Not known: frequency cannot be determined from the available data

- Tremor, rigid posture, mask-like face, slow movements and a shuffling, unsteady gait.

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website: www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and the blister strip after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the pack and other information

What substances are in this medicine?

Amlodipine (as besylate) Accord 5 mg tablets:

The active substance in this medicine is amlodipine. Each tablet contains 5 mg amlodipine (as besylate). The other substances in this medicine are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, disodium hydrogen citrate, crospovidone, croscarmellose sodium.

Amlodipine (as besylate) Accord 10 mg tablets:

The active substance in this medicine is amlodipine. Each tablet contains 10 mg amlodipine (as besylate). The other ingredients in this medicine are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, disodium hydrogen citrate, crospovidone, croscarmellose sodium.

What does Amlodipine (as besylate) Accord look like and what is in a package?

Amlodipine (as besylate) Accord 5 mg tablets:

White to off-white, round, biconvex tablets of approximately 6.6 mm.

Amlodipine (as besylate) Accord 10 mg tablets: 10 mg tablets:

Package sizes:

Blister pack:

5 mg: 10, 14, 20, 28, 30, 50, 60, 90, 98 and 100 tablets

10 mg: 10, 14, 20, 28, 30, 50, 60, 90, 98 and 100 tablets

HDPE bottle:

HDPE bottle:

Not all mentioned package sizes are marketed

Marketing authorization holder and manufacturer

Marketing authorization holder

Accord Healthcare B.V.

Winthontlaan

Winthontlaan 200

3526 KV Utrecht, Netherlands

Manufacturer

Accord Healthcare B.V.

Winthontlaan 200

3526 KV Utrecht,

Netherlands

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare Single Member S.A.
64th Km National Road Athens
Lamia, Schimatari, 32009, Greece

Registered under
5 mg: RVG 109577
10 mg: RVG 109579

This medicine is registered in EEA member states under the following names:

Name of the member state	Name of the medicine
Austria	Amlodipine Accord 5/10 mg Tablets
Cyprus	Amlodipine Accord 5 mg/10 mg Tablets
Czech Republic	Amlodipine Accord 5/10 mg Tablets
Denmark	Amlodipine Accord 5/10 mg Tablets
Estonia	Amlodipine Accord 5/10 mg
Finland	Amlodipine Accord 5 mg/10 mg tablet
Ireland	Amlodipine 5 mg/10 mg Tablets
Italy	AMLODIPINE ACCORD 5/10 MG TABLETS
Lithuania	Amlodipine Accord 5/10 mg tablets
Latvia	Amlodipine Accord 5/10 mg tablets
Netherlands	Amlodipine (as besylate) Accord 5/10 mg, tablets
Norway	Amlodipine Accord
Poland	Almiden
Portugal	Amlodipine Accord
Romania	Almiden 5 mg/10 mg tablets
Spain	Amlodipine Accord 5 mg/10 mg tablets
Sweden	Amlodipine Accord 5/10 mg tablets

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