

Patient Information Leaflet

SCHEDULING STATUS

S3

PENDINE 5 mg tablets

PENDINE 10 mg tablets

Amlodipine besilate

Sugar free.

Read all of this leaflet carefully before you start taking PENDINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PENDINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

4. Possible side effects

5. How to store PENDINE

6. Contents of the pack and other information

1. What PENDINE is and what it is used for

PENDINE contains the active substance amlodipine, which belongs to a group of medicines called calcium antagonists. It works by relaxing the blood vessels, so that the blood passes through the blood vessels more easily.

PENDINE has been prescribed for you in order to treat high blood pressure (hypertension) or a type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

PENDINE is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

PENDINE can be prescribed alone or in combination with other medicines.

2. What you need to know before you take PENDINE

Do not take PENDINE:

- If you are hypersensitive (allergic) to amlodipine, other calcium antagonists or to any of the other ingredients of PENDINE (listed in section 6).
- If you suffer from low blood pressure (hypotension).
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body) or aortic stenosis (narrowing of the aortic heart valve).
- If you suffer from heart failure after a heart attack.
- In combination with grapefruit juice.

Warnings and precautions***Talk to your doctor before taking PENDINE:***

- If you have heart failure (a condition where the heart cannot pump blood well).
- If you have porphyria.
- If you have liver problems.
- If you are over the age of 65 years.

Your doctor will not prescribe PENDINE to you if you were diagnosed with having a hypertensive crisis (severe increase in blood pressure).

Children and adolescents

PENDINE has not been studied in children under the age of 6 years. PENDINE should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3). For more information, talk to your doctor.

Other medicines and PENDINE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

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

- Azole antifungal medicines, such as ketoconazole and itraconazole (used to treat fungal infections).
- Protease inhibitors (used to treat human immunodeficiency virus [HIV] infections).
- Macrolide antibiotics, such as erythromycin and clarithromycin (used to treat certain infections).
- Verapamil or diltiazem (heart medicines).
- *Hypericum perforatum* (St. John's Wort, herbal medicine used to treat mild depression).
- Dantrolene (infusion for severe body temperature abnormalities).
- Tacrolimus, sirolimus, temsirolimus, and everolimus (immunosuppressant medicines used to prevent organ rejection after a transplant).
- Simvastatin (cholesterol lowering medicine).
- Ciclosporin (immunosuppressant medicine used to prevent organ rejection after a transplant).

If you take other medicines for angina such as nitroglycerin tablets under the tongue, long-acting nitrates or beta-blockers with PENDINE, your blood pressure may lower even more and you may feel very tired and weak.

PENDINE with food and drink

Do not eat grapefruit or drink grapefruit juice with PENDINE. 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 PENDINE.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Consult your doctor immediately if you become pregnant while taking this medicine.

If you are a woman of childbearing potential, you and your partner should ensure you are both using adequate contraception. The safety of PENDINE in human pregnancy has not been established.

Driving and using machines

PENDINE may cause dizziness, headaches, tiredness or nausea. Do not drive a vehicle or operate machinery until you know how PENDINE affects you, as your ability to react may be impaired.

PENDINE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take PENDINE

Do not share medicines prescribed for you with any other person.

Always take PENDINE exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Adults

The usual starting dose of PENDINE is 5 mg once a day, however the dose may be increased to 10 mg per day (taken as a single dose).

In patients suffering from hypertension, PENDINE may be used either on their own or in combination with other medicines for hypertension.

If you suffer from liver problems, your doctor will decide the most suitable dose for you.

The tablets should be swallowed with a glass of water and should be taken the same time each day.

PENDINE tablets may be taken with or without food.

Use in children and adolescents

The usual starting dose for children aged 6 – 17 years is 2,5 mg which can be increased to 5 mg once a day.

Your doctor will tell you how long your treatment with PENDINE will last. If you have the impression that the effect of PENDINE is too strong or too weak, tell your doctor or pharmacist.

Do not stop taking your medicine without consulting your doctor first.

If you take more PENDINE than you should

If you have taken an overdose of PENDINE, you may appear flushed (your skin will look red) and your heart may beat faster than usual. Your blood pressure may be lower than usual for a long time which can make you feel dizzy, lightheaded, faint or weak. If your blood pressure drop is severe enough, shock can occur (pale, cold, clammy skin with difficulty breathing) and you could lose consciousness.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may only develop later (24 – 48 hours after intake). You may stop breathing and need to be ventilated.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take PENDINE

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose.

Do not take a double dose to make up for the forgotten doses.

4. Possible side effects

PENDINE can have side effects.

Not all side effects reported for PENDINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PENDINE, please consult your health care provider for advice.

If any of the following happens, stop taking PENDINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PENDINE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Heart attack (myocardial infarction), irregular, slow or fast heartbeat (arrhythmia), chest pain.
- Bleeding or bruising more easily than normal.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Inflammation of the liver, jaundice (yellowing of the skin and/or eyes).
- Severe skin reactions including intense skin rash, hives, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes, such as Stevens-Johnson Syndrome or toxic epidermal necrolysis (painful, blistering or peeling skin rash), sensitivity to light.
- Shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache, dizziness, sleepiness.
- Palpitations (a quicker or irregular heartbeat), flushing.
- Abdominal pain, nausea (feeling sick).
- Altered bowel habits, diarrhoea, constipation, indigestion.
- Visual disturbances, double vision.
- Swelling of the ankles, muscle cramps.
- Feeling tired, weakness.

Less frequent side effects

- Erythema multiforme (large, symmetrical red blotches that appear all over the skin in a circular pattern).
- Excess sugar in blood (hyperglycaemia).
- Feeling depressed, mood changes, anxiety, confusion, inability to sleep.
- Tightening of the muscles, tingling or numbness of your hands and feet (pins and needles), loss of pain sensation, shaking or trembling, taste abnormalities, movement disorder.
- Ringing in the ears.
- Low blood pressure, fainting, inflammation of the blood vessels.
- Coughing, runny nose.
- Vomiting (being sick), swelling or soreness of the gums, dry mouth, inflamed pancreas (causing nausea, vomiting, fever, pain in your stomach area radiating to your back), gastritis (inflammation of the stomach lining).
- Abnormal liver function.
- Hair loss, red patches or other skin colour changes, increased sweating, skin rash, itchy skin.
- Back pain, muscle or joint pain.
- Increased need to urinate, increased need to urinate at night, disorder in passing urine.
- Weight increase or decrease.
- Enlargement of the male breasts, inability to obtain an erection.
- Generally feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of PENDINE.

5. How to store PENDINE

- Store at or below 25 °C.
- Store in a dry place.
- Keep the blister strips in the outer carton until required for use. Protect from light.
- **Store all medicines out of reach of children.**
- Do not use after the expiry date printed on the blister strip or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PENDINE contains

The active ingredient is amlodipine besilate.

PENDINE 5: Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine.

PENDINE 10: Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine.

The inactive ingredients are calcium hydrogen phosphate (anhydrous), magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What PENDINE looks like and contents of the pack

PENDINE 5: White, round, flat, bevel edged uncoated tablets with score on one side and 'PENDINE' debossed along the periphery on the other side.

PENDINE 10: White, round, flat, bevel edged uncoated tablets with score on one side and 'PENDINE' debossed along the periphery on the other side.

PENDINE 5: Aluminium foil blisters containing 10 tablets. 3 blister strips are packed in an outer carton.

PENDINE 10: Aluminium foil blisters containing 10 tablets. 3 blister strips are packed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

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