Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL AMLODIPINE 5 mg

AUSTELL AMLODIPINE 10 mg

SCHEDULING STATUS

S3

AUSTELL AMLODIPINE 5 mg TABLETS

AUSTELL AMLODIPINE 10 mg TABLETS

Amlodipine besylate

Sugar free

Read all of this leaflet carefully before you start taking AUSTELL AMLODIPINE

- 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.
- AUSTELL AMLODIPINE 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 AUSTELL AMLODIPINE is and what it is used for
2. What you need to know before you take AUSTELL AMLODIPINE
3. How to take AUSTELL AMLODIPINE

4. Possible side effects

5. How to store AUSTELL AMLODIPINE

6. Contents of the pack and other information

1. What AUSTELL AMLODIPINE is and what it is used for

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

AUSTELL AMLODIPINE is used to treat high blood pressure (hypertension) and a type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina. AUSTELL AMLODIPINE is also used to reduce the risk of fatal and non-fatal heart disease or stroke.

AUSTELL AMLODIPINE can be used alone or with other medicines to treat these conditions.

2. What you need to know before you take AUSTELL AMLODIPINE

Do not take AUSTELL AMLODIPINE tablets

- If you are sensitive (allergic) to amlodipine or any of the other ingredients of AUSTELL AMLODIPINE (listed in section 6)
- If you have had an allergic reaction to other medicines of this type.
- In combination with grapefruit juice
- If you have severe low blood pressure (hypotension)
- If you have 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)

- If you suffer from heart failure after a heart attack.

Warnings and precautions

Take special care with AUSTELL AMLODIPINE

• If you are taking other medicines such anti-fungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat HIV (ritonavir). Using these medicines together with AUSTELL AMLODIPINE may decrease the blood pressure even further (see Other medicines and AUSTELL AMLODIPINE)

• If you are elderly and if your doctor needs to increase your dose, this should happen with care

• If you have severe kidney disease

• If you have liver disease and if your doctor needs to increase your dose. You will be closely monitored by your doctor if you have severe liver failure.

• If you have heart failure (a condition where the heart cannot pump blood well).

Children and adolescents

AUSTELL AMLODIPINE has not been studied in children under the age of 6 years. AUSTELL AMLODIPINE should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see How to take AUSTELL AMLODIPINE).

Other medicines and Austell Amlodipine

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are already taking or planning to take any of the following medicines as they may interact with AUSTELL AMLODIPINE

- Cholesterol-lowering medicine (simvastatin).
- Heart medicines (diltiazem).
- Anti-fungal medicines (ketoconazole, itraconazole) (see Warnings and precautions).
- Antibiotics (erythromycin, clarithromycin, rifampicin).
- Protease inhibitors used to treat HIV (ritonavir) (see Warnings and precautions).
- St. John's Wort (hypericum perforatum).
- Immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin).
- Dantrolene (infusion for severe body temperature abnormalities)

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

AUSTELL AMLODIPINE with food and drink

Do not eat grapefruit or drink grapefruit juice with AUSTELL AMLODIPINE.

Pregnancy, breastfeeding and fertility

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 AUSTELL AMLODIPINE.

If you are a woman of childbearing potential, you and your partner should ensure you are both using adequate contraception.

The safety of AUSTELL AMLODIPINE in human pregnancy has not been established.

AUSTELL AMLODIPINE has been shown to pass into breast milk.

There is insufficient information regarding the potential effect of AUSTELL AMLODIPINE on fertility.

Driving and using machines

AUSTELL AMLODIPINE 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.

It is not always possible to predict to what extent AUSTELL AMLODIPINE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AUSTELL AMLODIPINE affects them.

3. How to take AUSTELL AMLODIPINE

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

Always take AUSTELL AMLODIPINE exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Adults

The usual initial dose is 5 mg once daily. The dose can be increased to 10 mg once daily.

Children and adolescents

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

Duration of administration

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

Continue taking AUSTELL AMLODIPINE until your doctor tells you to stop at which time it should be done gradually.

Method of administration

AUSTELL AMLODIPINE tablets may be taken with or without food. Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

If you take more AUSTELL AMLODIPINE than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 - 48 hours after intake.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take AUSTELL AMLODIPINE

It is important to take your AUSTELL AMLODIPINE tablets regularly at the same time each day. 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 forgotten individual doses.

If you stop taking AUSTELL AMLODIPINE

Take AUSTELL AMLODIPINE for as long as your doctor recommends. Don’t stop unless your doctor advises you to. Your condition may return if you stop using this medicine before you are advised.

4. Possible side effects

AUSTELL AMLODIPINE can have side effects.

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

If any of the following happens, stop taking AUSTELL AMLODIPINE tablets 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
- 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)
- large, symmetrical red blotches that appear all over the skin in a circular pattern (erythema multiforme)
- heart attack
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to AUSTEL AMLODIPINE. 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:

- abnormal heart beat
- severe abdominal and back pain accompanied with feeling very unwell (which may be caused by an inflamed pancreas).

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 especially when standing up, sleepiness (especially at the beginning of treatment)
- very fast heartbeat (heart palpitations), hot or warm feeling in your face (flushing)
- stomach pain, feeling sick (nausea)
- swelling of your legs or ankles, tiredness.

Less frequent side effects

- too few white blood cells, too few blood platelets, which may result in unusual bruising or easy bleeding
- too much sugar in the blood (hyperglycaemia)
- mood changes, anxiety, depression, sleeplessness

- tightening of the muscles, loss of pain sensation, numbness or tingling sensation, fainting, taste abnormalities, a disorder of the nerves which can cause muscular weakness, tingling or numbness, a disorder combining rigidity, trembling and/or movement disorder
- visual disturbances
- ringing in the ears
- low blood pressure, inflammation of the blood vessels
- cough, shortness of breath, sneezing/running nose (rhinitis)
- change in bowel habits, dry mouth, indigestion, swelling or bleeding of the gums, inflammation of the pancreas, vomiting
- hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- joint or muscle pain, back pain, muscle cramps
- increased need to urinate especially at night, pain when urinating, increased number of times of passing urine
- inability to obtain an erection, discomfort or enlargement of the breasts in men
- pain, feeling unwell, weakness, chest pain
- increase or decrease in weight
- confusion
- itching, rash, swelling under the skin, red blotchy skin
- 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

- sensitivity to light.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AUSTELL AMLODIPINE**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store AUSTELL AMLODIPINE

Store all medicines out of reach of children.

- Store at or below 25 °C in the original packaging. Protect from light.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use this medicine after the expiry date stated on the label and carton.

6. Contents of the pack and other information

What AUSTELL AMLODIPINE contains

- The active substance is amlodipine.
- The other ingredients are calcium hydrogen phosphate, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous, sodium starch glycolate.

AUSTELL AMLODIPINE 5 mg

Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine.

AUSTELL AMLODIPINE 10 mg

Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine.

What AUSTELL AMLODIPINE looks like and contents of the pack

AUSTELL AMLODIPINE 5 mg Tablets

White to off- white, round, biconvex, uncoated tablets, with ‘5’ debossing on one side.

AUSTELL AMLODIPINE 10 mg Tablets

White to off- white, round, biconvex, uncoated tablets, with ‘10’ debossing on one side.

AUSTELL AMLODIPINE 5 mg is supplied in blister packs (opaque PVDC coated PVC film and aluminium foil) of 28, 30, 56 or 84 tablets.

AUSTELL AMLODIPINE 10 mg is supplied in blister packs (opaque PVDC coated PVC film and aluminium foil) of 28, 30, 56 or 84 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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AUSTELL AMLODIPINE 10 mg: A39/7.1/0546

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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