

Austell Laboratories (Pty) Ltd, 42/20.1.2/0040-41, AUSTELL-PEN VK 125/250, Powder for oral solution

Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL-PEN VK 125/250

SCHEDULING STATUS: S4

AUSTELL-PEN VK 125 (POWDER FOR ORAL SOLUTION)

Phenoxymethylpenicillin

Contains sugar

Each 5mL contains 2610,00 mg of Sucrose and

Saccharin sodium: 0,50 mg

AUSTELL-PEN VK 250 (POWDER FOR ORAL SOLUTION)

Phenoxymethylpenicillin

Contains sugar

Each 5mL contains 2550,00 mg of Sucrose and

Saccharin sodium: 1,0 mg

Read all of this leaflet carefully before you start taking-AUSTELL-PEN VK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- AUSTELL-PEN VK 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-PEN VK is and what it is used for
2. What you need to know before you take AUSTELL-PEN VK
3. How to take AUSTELL-PEN VK

4. Possible side effects
5. How to store AUSTELL-PEN VK
6. Contents of the pack and other information

1. What AUSTELL-PEN VK is and what it is used for

AUSTELL-PEN VK is used to prevent recurrence of a condition known as rheumatic fever, which is a type of inflammatory disease which can affect the connective tissue of the heart, blood vessels and joints.

It is indicated in the treatment of mild to moderate middle ear infections, sinusitis, and pharyngitis (infection of the throat).

2. What you need to know before you take AUSTELL-PEN VK

Do not take AUSTELL-PEN VK if you:

- Are allergic to Phenoxymethylpenicillins or Cephalosporin-type antibiotic or any of the ingredients of AUSTELL-PEN VK (listed in Section 6).
- Have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic
- Use in diarrhoea
- Use in fevers

Warnings and precautions

Take special care with AUSTELL PEN-VK

- if you suffer from any stomach problems, e.g. vomiting
- if you suffer from any kidney problems
- if you suffer from allergies and/or asthma

Other medicines and AUSTELL-PEN VK

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

AUSTELL-PEN VK can affect or be affected by other medicines you are using, Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are taking

- Probenecid, Sulfapyrazone (medicines used to treat gout and other conditions which require lowering of blood uric acid levels.)
- Methotrexate (a medicine used to treat cancers and psoriasis)
- Guar gum (a medicine used to treat diarrhoea irritable bowel syndrome)
- Neomycin, Chloramphenicol, Erythromycin, Tetracyclines can result in decreased absorption of AUSTELL-PEN VK.
- Anticoagulants (medicines that prevent the clotting of blood).
- Oral typhoid vaccine (penicillin can stop this from working).

Pregnancy and Breast feeding:

- 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-PEN VK.

Driving and using machines

This medicine should not affect your ability to drive or to use machinery.

It is not always possible to predict to what extent AUSTELL-PEN VK 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-PEN VK affects them.

3. How to take AUSTELL-PEN VK

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oral solution

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

Always take AUSTELL-PEN VK exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

1) Streptococcal infections:

Adults: 125 to 250 mg every 4 hours

Children: up to 1 year 60 mg every 6 hours

1 to 5 years: 125 mg every 6 hours.

6 to 12 years: 250 mg every 6 hours

2) Rheumatic fever prophylaxis: 125 mg every 12 hours.

DIRECTION FOR RECONSTITUTING: 100 mL syrup. Add 65 mL water and shake well to dissolve.

Duration of administration

Your doctor will tell you how long your treatment with AUSTELL-PEN VK will last. Do not stop treatment early because Streptococcal pharyngitis must be treated for a minimum of 10 days. If you have the impression that the effect of AUSTELL-PEN VK is too strong or too weak, tell your doctor or pharmacist.

Method of administration

Shake the bottle well before use.

If you take more AUSTELL-PEN VK than you should

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

If you forget to take AUSTELL-PEN VK

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

If you stop taking AUSTELL-PEN VK

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

AUSTELL-PEN VK can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

- diarrhoea, transient nausea and heartburn,
- hypersensitivity reactions like rash, hives and angio-oedema (symptoms are swelling of the tongue and lips for example),
- severe peeling/blistering of the skin,
- neutropenia (decreased number of leukocytes in the blood)-₁
- nephropathy and interstitial nephritis – (a type of kidney infection, symptoms are for example, an abnormal urine sediment)-₁
- seizures,
- sore mouth/tongue-
- serum sickness like reactions (characterised by fever, chills, joint pains and oedema),

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These are very serious side effects. If you have them, you may have had a serious reaction to AUSTELL-PEN VK. 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:

- stomach pain or cramps,
- vomiting,
- diarrhoea.

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:

- extremely low blood pressure, swelling of the throat, difficulty breathing and loss of consciousness,
- rash and shedding of skin,
- hives, itchy skin with an odor,

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

Less frequent side effects:

- sore mouth,
- black hairy tongue,
- sore throat,
- problems with blood clotting (unusual bleeding or bruising),
- infections or fever (may be caused by low white blood cells),
- anaemia (may cause lack of energy or tiredness),

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- kidney problems, which might cause blood in the urine or reduced amounts of urine.

Side effects with frequency unknown:

- Rash with blisters arranged in a circle with crushing or like a string of pearls (linear IgA disease).
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac disease (Kounis syndrome).

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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-PEN VK.

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-PEN VK

Unconstituted powder: Store in a dry place at or below 25 °C.

Reconstituted oral solution: Store for 7 days in a refrigerator.

Shake bottle before use.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage system (e.g toilets).

6. Contents of the pack and other information

What AUSTELL-PEN VK contains

The active ingredient in **AUSTELL-PEN VK 125/250** is phenoxymethylpenicillin potassium. The powder for oral solution is available in strengths of 125 mg and 250 mg.

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The other ingredients are: sucrose, strawberry flavour, red dye E124 and sodium saccharin.

What AUSTELL-PEN VK looks like and contents of the pack

White-Opaque HDPE bottle of 100 ml, with a tamper evident cap.

AUSTELL-PEN VK 125/250 is a light pink powder with an odour of strawberry, when reconstituted,
a clear pink solution is obtained.

Holder of Certificate of Registration

Austell Laboratories (Pty) Ltd,
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South Africa.

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Registration/Application numbers

AUSTELL-PEN VK 125: 42/20.1.2/0040

AUSTELL-PEN VK 250: 42/20.1.2/0041

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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