Approved Professional Information for Medicines for Human Use:

AUSTELL-PEN VK 125/250

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

AUSTELL-PEN VK 125 (POWDER FOR ORAL SOLUTION)

AUSTELL-PEN VK 250 (POWDER FOR ORAL SOLUTION)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

AUSTELL-PEN VK 125:

Each 5 ml after reconstitution contains phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 125 mg.

Contains sugar: Sucrose (castor grade): 2610,00 mg

Contains sweetener: Saccharin sodium: 0,50 mg

AUSTELL-PEN VK 250:

Each 5 ml after reconstitution contains phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 250 mg.

Contains sugar: Sucrose (castor grade): 2550,00 mg

Contains sweetener: Saccharin sodium: 1,0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AUSTELL-PEN VK is used prophylactically to prevent recurrence of rheumatic fever.

It is also indicated in the treatment of:

- Mild to moderate infections caused by sensitive organisms.
- Pneumococcal infections of the middle ear.
- Streptococcal otitis media and sinusitis.
- Streptococcal pharyngitis caused by *Streptococcus pyogenes.*

4.2 Posology and method of administration

Posology

(1) Streptococcal infection:

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.

Method of administration

AUSTELL-PEN VK is for oral administration.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

- Hypersensitivity to the Phenoxymethylpenicillins or Cephalosporins to any of the excipients listed in section 6.1.
- Use in Dysentry, and typhus, and other infections caused by penicillin resistant microbes such as *Brucella* and *E.coli*.
- For treatment of trivial disorders.

4.4 Special warnings and precautions for use

- Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma. All degrees of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin. These reactions are more likely to occur in individuals with a history of sensitivity to penicillins cephalosporins and other allergens. Enquiries should be made for such a history before therapy is begun.
- If any allergic reaction occurs, the medicine should be discontinued and the patient treated with the usual medicines (e.g. adrenaline and other pressor amines, antihistamines and corticosteroids).

  Oral therapy should not be relied upon for patients with severe illness, or with nausea, vomiting gastric dilation, achalasia or intestinal hypermotility.
- Occasionally patients do not absorb therapeutic amounts of orally administered penicillin.
- Administer with caution in the presence of markedly impaired renal function, as safe dosage may be lower than the usually recommended doses.
- Streptococcal infections should be treated for a minimum of 10 days, and post therapy cultures should be performed to confirm the eradication of the organisms.
- Prolonged use of antibiotics may promote the over growth of non-susceptible organisms including fungi. If super infection occurs, appropriate measures should be taken.

Sucrose

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Interactions

- Aminoglycosides: Neomycin is reported to reduce the absorption of phenoxymethylpenicillin.
- Anticoagulants: Penicillins may interfere with anticoagulants control.
- Bacteriostatic antibiotics: Certain bacteriostatic antibiotics such as Chloramphenicol, Erythromycin and Tetracyclines have been reported to antagonise the bactericidal activity of penicillins and concomitant use is not recommended.
- Guar gum: Reduced absorption of phenoxymethylpenicillin.
- Methotrexate: Use of Phenoxymethylpenicilin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity.
- Probenecid: Reduced excretion of phenoxy methylpenicillin by competing with it for renal tubular secretion.
- Sulfinpyrazone: Excretion of penicillins reduced by sulfinpyrazone.
- Typhoid vaccine (Oral): Penicillins may inactivate oral typhoid vaccine if ingested concomitantly.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

a) Summary of the safety profile

The most common reactions to oral penicillin are gastrointestinal effects and hypersensitivity reactions. Although hypersensitivity reactions have been reported much less frequently after oral than after parenteral therapy, it should be remembered that all forms of hypersensitivity, including fatal anaphylaxis have been observed with oral penicillin.

b) Tabulated list of adverse reactions

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and postmarket spontaneous reports with phenoxymethylpenicillin

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Blood and lymphatic system disorders		Neutropenia, haemolytic anaemia, leucopenia, prolongation of bleeding time and defective platelet function.	

Cardiac disorders			Kounis syndrome
Immune system disorders	Allergic skin reactions such as exfoliative dermatitis, anaphylaxis, angio-oedema, urticaria and some maculopapular rashes.		
Nervous system disorders			Convulsions and other signs of toxicity to the central nervous system (CNS).
Gastrointestinal disorders	Transient nausea, diarrhoea, pseudomembraneous colitis.		
Hepatobiliary disorders		Hepatitis and cholestatic jaundice	
Skin and	Urticarial, erythematous or	Exfoliative dermatitis	linear IgA

subcutaneous tissue disorders	mobilliform rash and pruritus		
Renal and urinary disorders		Nephropathy and interstitial nephritis. Care should be exercised when high doses are given to patients with renal impairment because of the risk of neurotoxicity.	
General disorders and administration site conditions		Sore mouth/tongue, black hairy tongue.	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via medsafety@austell.co.za.

4.9 Overdose

Any form of actual toxicity of phenoxymethylpenicillin is rare and doses of 8 g have been well tolerated.

Signs and symptoms

A large oral overdose of penicillin may cause nausea, vomiting, stomach pain, diarrhoea, and rarely, major motor seizures. If other symptoms are present, consider the possibility of an allergic reaction. Hyperkalaemia may result from overdosage, particularly for patients with renal insufficiency.

Treatment

No specific antidote is known. Symptomatic and supportive therapy is recommended. Activated charcoal with a cathartic, such as sorbitol may hasten drug elimination. Penicillin may be removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 20.1.2 Penicillins.

Pharmacotherapeutic group:

ATC Code: J01C E02.

Mechanism of action

Phenoxymethylpenicillin is a narrow spectrum penicillin.

It exerts its action on growing and dividing bacteria by inhibiting bacterial cell-wall

synthesis. Its action is inhibited by penicillinase.

It has a bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria, spirochaetes and actinomyces.

5.2 Pharmacokinetic properties

Phenoxymethylpenicillin is resistant to inactivation by gastric acid. Absorption is variable with about 60% of an oral dose being absorbed. Peak plasma concentrations of 3 to 5 µg/ml have been observed 30-60 minutes after a dose of 500 mg. The effect of food on absorption appears to be slight. The plasma half-life of phenoxymethylpenicillin is about 30-60 minutes and may be increased to about 4 hours in severe renal impairment. About 80% is reported to be protein bound. Phenoxymethylpenicillin is widely distributed at varying concentrations in body tissues and fluids. It appears in significant amounts in the bile, liver, kidney, semen, joint fluid and intestine. It diffuses across the placenta into the foetal circulation and small amount appears in breast milk.

It is metabolised in the liver. Several metabolites have been identified including penicilloic acid. The unchanged medicine and metabolites are excreted rapidly in the urine. Only small amounts are excreted in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Strawberry flavour 17 .41 .05

Red dye (Anstead) 1578 8124

Sucrose (castor grade)

Saccharin sodium

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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.

Keep well closed.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

Direction for reconstitution: 100 ml syrup. Add 65 ml water and shake well to dissolve.

Shake the bottle well before use.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Austell Laboratories (Pty) Ltd,

52 Mineral Crescent,

Crown ext 3,

Johannesburg, 2092,

South Africa.

8. REGISTRATION NUMBER

AUSTELL-PEN VK 125: 42/20.1.2/0040

AUSTELL-PEN VK 250: 42/20.1.2/0041

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 August 2011

10. DATE OF REVISION OF THE TEXT

31.03.2025