SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

PHENOXYMETHYLPENIC1LLIN POTASSIUM TABLETS BP 250 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 250 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Shiny white, flat tablets with k logo on one side and break line on the other

4.1. Therapeutic Indications

Phenoxymethylpenicillin potassium is orally active penicillin indicated for treatment of bacterial infections where a sensitive organism is suspected or proven.
Phenoxymethylpenicillin should not be used for serious infections because absorption can be unpredictable and plasma concentrations variable.
Lower respiratory tract: pneumonia, bronchitis
Upper respiratory tract: bacterial pharyngitis, otitis media
Others: skin and soft tissues infections, scarlatina, erysipelas, prophylaxis of rheumatic fever and pneumococcal infection prophylaxis in asplenia or patients with sickle cell disease.

Consideration should be given to official guidance on the appropriate use of antibacterial agent.

4.2. Posology and Method of Administration

The dose will depend upon the severity, type and site of infection,
In general the treatment must be continued 1-3 days after improvement of the symptoms.

For children
-1-5 years of age 125 mg every 6 hours
- 6-11 years of age 250 mg every 6 hours or as prescribed

For adults (including elderly)
Standard dosage: 250-500 mg every 6 hours or as directed by a medical practitioner.

Prevention of recurrence of rheumatic fever: 250mg twice daily

Adult	500rng every 12 hours
Child under 5 years	125mg every 12 hours
Child 6-11 years	250mg every 12 hours

To avoid late complications (rheumatic fever), infections with β-haemolytic streptococci should be treated for 10 days.

Special dosage: The elimination of phenoxymethylpcnicillin potassium is reduced in case of
renal insufficiency.
The dose interval should be adjusted to every 8 hours to 12 hours according to the seventy of
renal impairment.
The recommended dose is to be taken about half an hour before meals.

Method of administration:
Oral.

The treatment of acute otitis media with penicillin V should be limited to 5 days. However, 5-10 days treatment may be recommended in patients with potential for complications.

4.3 Contraindications

Phenoxymethylpenicillin potassium should not be given to patients with a history of penicillin hypersensitivity.

Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics e.g. cephalosporins. Severe acute infections should not be treated with phenoxymethylpenicillin.

4.4 Special warnings and precautions for use

All degree of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin. These reactions are more likely occur in individuals with a history of sensitivity to penicillin, cephalosporin and other allergens.

Enquiry should be made for such a history before therapy with a penicillin begins. If an allergic reactions occurs, the drug should be discontinued and the patient treated with the usual agents (eg. Adrenaline and other pressor amines, antihistamines and other corticosteroids).

Oral therapy should not be relied upon in patients with severe illness, or with nausea, vomiting, gastric dilation, cardiospam or intestinal hypermotility.

Occasionally, patients do not absorb therapeutics amounts of orally administered penicillin.

Administer with caution in the presence of markedly impaired renal function, as the safe dosage may be lower than the usually recommended.

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 overgrowth of non-susceptible organisms including fungi. If super-infection occurs, appropriate measure should be taken.

Caution should be used when treating patients with a history of antibiotics-associated colitis.

During treatment with phenoxymethylpenicillin non-enzymatic glusose tests may be false –positive**.**

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid delays the elimination of penicillin through the kidneys and thus prolongs its action.
Phenoxymenthylpenicillin reduces the excretion of the cytotoxic drug, methotrexate.
Avoid concomitant administration with bacteriostatics antibiotics such as tetracycline, erythromycin, chloramphenicol and sulphonamides because it can diminish the effect of Phenoxymethylpenicillin potassium.
In case of simultaneous administration of Phenoxymenthylpenicillin and oral contraceptives, the hormonal contraception can lose its efficacy. Patients should be advised to use additional forms of contraceptives precautions while taking Phenoxymethylpenicillin.
The simultaneous administration of guar gum diminishes the absorption of penicillin.
Phenoxymethylpenicillin has the following interaction information:
Neomycin – absorption of Phenoxymethylpenicillin reduced by neomycin.
Coumarin – common experience in anticoagulant clinics is that INR can be altered by a course of broad-spectrum penicillins such as ampicillin, although studies have failed to demonstrate an interaction with coumarins.
Phenindione – common experience in anticoagulant clinics is that INR can be altered by a course of broad-spectrum penicillins such as ampicillin, although studies have failed to demonstrate an interaction with phenindione.
Sulfinpyrazone - excretion of penicillin reduced by sulfinpyrazone.
Typhoid Vaccines - antibacterials inactive oral typhoid vaccine.

4.6 Pregnancy and lactation

Pregnancy

Animal studies with phenoxymethylpenicillin potassium have shown no teratogenic effects.

Phenoxymethylpenicillin potassium has been in extensive clinical use and suitability in human pregnancy has been well documented in clinical studies. However, as with other drugs, caution should be exercised when prescribing to pregnant patients.

Lactation

Breast feeding is not contraindicated with phenoxymethylpenicillin potassium. Trace quantities of phenoxymethylpenicillin potassium can be detected in breast milk. While adverse effects are apparently rare, two potential problems exist for nursing infant:

- modification of bowel flora
- direct effects on the infant such as allergy/sensitisation

Caution should therefore be exercised when prescribing for the nursing mother

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Hypersensitivity

Although reactions have been reported much less frequently after oral than after parenteral therapy, it should be remembered that all degrees of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin.

The hypersensitivity reactions noted include urticaria, fever, joint pains, rashes, angioedema, anaphylaxis, serum sickness like reactions, haemolytic anaemia and interstitial nephritis.

Gastro-intestinal tract

Phenoxymethylpenicillin potassium is generally well tolerated. Occasionally soft stools occur and they do not require the interruption of the treatment.

Digestive troubles with nausea and/or vomiting rarely appear. Severe and persistent diarrhoeas can be the symptoms of pseudomembranous colitis. This requires immediate attention and treatment with an appropriate antibiotherapy (i.e. vancomycin).

Blood

Possible effects on the blood composition: neutropenia or leucopenia. thrombocytopenia, haemolytic anaemia and coagulation disorders.

Central nervous system

Central nervous system toxicity, including convulsions, has been reported. especially following high doses or in severe renal impairment. Paraesthesia has been reported with prolonged use.

4.9 Overdose

Cases of intended or accidental overdosage should be brought under medical supervision for symptomatic treatment. It is advisable to monitor blood levels in patients with renal malfunction.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Phenoxymethylpenicillin potassium is a beta lactam antibiotic with bactericidal action against Gram-positive bacteria and Gram-negative cocci. Its antimicrobial action is similar to that of benzyl penicillin. Phenoxymethylpenicillin potassium is usually active against the following organisms:

Gram-positive aerobes and anaerobes including

Bacillus anthracis

Clostridium perfringens

Clostridium tetani

Corynebacterium diphtheriae

Erysipelothrix rhusiopathiae

Listeria monocytogenes

Peptostreptococcus spp.

Streptococcus agalactiae (Group *B)*

Streptococcus pneumoniae

Streptococcus pyogenes (Group *A)*

Gram-negative including

Neisseria meningitidis

Neisseria gonorrhoeae

Phenoxymethylpenicillin potassium is inactivated by penicillinase and other beta lactamases.

Phenoxymethylpenicillin binds to penicillin-binding proteins located on the inner membrane of the bacterial cell wall. Phenoxymethylpenicillin binds to and inactivates these proteins resulting in weakening of the bacterial cell wall and lysis.

5.2 Pharmacokinetic properties

Phenoxymethylpenicillin is stable under acidic conditions so it can be administered by oral route.

Phenoxymethylpenicillin is rapidly, but incompletely absorbed after oral administration and the absorption level is around 60%. The simultaneous administration of food slightly decreases the peak plasma concentration of phenoxymethylpenicillin, but does not appear to affect the extent of absorption. Peak plasma concentrations are reached in about 45 minutes. The peak plasma concentration increases approximately in proportion with increased doses.

Phenoxymethylpenicillin is partially metabolised to inactive penicilloic acid by hydrolysis of the lactam ring. This metabolism occurs in the liver.

Phenoxymethylpenicillin passes into the tissues (volume of distribution about 0.2 1.kg-1 of body weight.

The plasma protein binding is about 80%.

About 40% of the dose is eliminated in the urine either as under unchanged or as penicilloic acid in the first 10 hours after oral administration.

The plasma half-life of phenoxymethylpenicillin is about *45* minutes. It is however extended in case of renal insufficiency.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The excipients in the tablet are: lactose, maize starch, magnesium stearate and pregelatinised starch.

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf life of the product is 36 months.

6.4 Special precautions for storage

Phenoxymethylpenicillin Potassium Tablets should be kept out of reach of children in a dry place below 25°C.

6.5 Nature and contents of container

Polypropylene container with pilfer proof polyethylene closure containing 28 or 100 or 500 or 1000 tablets.

Blister packs

Pack size: 28, 100, 112, 250, 252, 500, 504, 1000, 1008 tablets

6.6 Special precautions for disposal

The tablets should be swallowed with water.

7. Marketing Authorisation Holder

SK MEDICINES LTD
Lagos, Nigeria.

8 MARKETING AUTHORISATION NUMBER(S)

NA

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

NA

10 DATE OF REVISION OF THE TEXT

24/03/2020