Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Phenoxymethylpenicillin Sugar Free 125 mg/5 ml Powder for Oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains 138.6mg of Phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 125mg.

Also contains 955.5mg/5ml of Sorbitol (E420).
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Phenoxymethylpenicillin 125mg is a white to off-white fine powder, which when reconstituted as directed, yields a colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Phenoxymethylpenicillin and phenoxymethylpenicillin potassium are indicated in the treatment of mild to moderately severe infections associated with micro-organisms whose susceptibility to penicillin is within the range of serum levels attained with the dosage form.

Phenoxymethylpenicillin is indicated for the treatment of the following infections (See Section 4.4 and 5.1)

Streptococcal infections:
Pharyngitis
Scarlet fever
Skin and soft tissue infections (e.g. erysipelas)
Pneumococcal infections:
Pneumonia
Otitis media
Vincent's gingivitis and pharyngitis

Phenoxymethylpenicillin is also indicated for (see Section 5.1):

Prophylaxis of rheumatic fever and/or chorea
Prophylaxis of pneumococcal infection (e.g. in asplenia and in patients with sickle cell disease)
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

For oral administration only.

The dosage and frequency of Phenoxymethylpenicillin depends on the severity and localisation of the infection and expected pathogens.

Phenoxymethylpenicillin 250 mg is approximately equivalent to 400,000 units.

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

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

Theusual dosage recommendations are as follows:

Adults and children over12 years: 250-500 mg every six hours
Children:Infants (up to 1 year): 62.5mg every 6 hours. The total daily dose is 250mg in divided doses.
1-5 years: 125 mg every six hours
6-12 years: 250 mg every six hours

Prophylactic Use

Prophylaxis of rheumatic fever/ chorea: 250 mg twice daily on a continuing basis
Prophylaxis of pneumococcal infection (e.g. in asplenia and in sickle cell disease):
Adults and children over 12 years: 500mg every 12 hours.
Children 6-12 years: 250mg every 12 hours.
Children below 5 years: 125mg every 12 hours.

Elderly

The dosage is as for adults. The dosage should be reduced if renal function is markedly impaired.

Renal impairment

The dosage should be reduced if renal function is markedly impaired.

Hepatic impairment

Dosage adjustment may be necessary in patients with impaired liver function when they also have renal failure. In this situation the liver may be a major excretion route.

Method of Administration

Ideally, each dose should be given half an hour before (or at least three hours after) a meal, as ingestion of phenoxymethylpenicillin with meals slightly reduces the absorption of the drug.

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

4.3 Contraindications

Hypersensitivity to Penicillin including ampicillin or to any of the ingredients listed in section 6.1 and should be used with caution in patients with known histories of allergy.

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 drug should be discontinued and the patient treated with the usual agents (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 result in the development of superinfection due to organisms resistant to that anti-infective including Pseudomonas and Candida. If super infection occurs, appropriate measures should be taken.
Cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of penicillins. These are serious and potentially life threatening cutaneous conditions. Patients should be advised of the signs and symptoms of SJS and TEN (e.g., progressive skin rash often with blisters or mucosal lesions) and instructed to discontinue use immediately and seek urgent medical attention.
In patients undergoing long-term Phenoxymethylpenicillin treatment the complete and differential blood count, as well as the liver and kidney function, should be monitored.
Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis. As this condition may be life-threatening phenoxymethylpenicillin should be withdrawn immediately and treatment guided by bacteriologic studies. It should be noted that each 125mg dose contains about 1/3mmol of potassium, which may be harmful to people on low potassium diets and may cause stomach upset, diarrhoea and hyperkalaemia. High doses should be used with caution in patients receiving potassium-containing drugs or potassium sparing-diuretics.
Severe empyema, bacteraemia, pericarditis, meningitis and arthritis should not be treated with Penicillin V during the acute phase.
Patients with a past history of rheumatic fever receiving continuous prophylaxis may harbour penicillin-resistant organisms. In these patients, the use of another prophylactic agent should be considered.
Oral penicillin should not be used as adjunctive prophylaxis for genito - urinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy and child birth.

Information about excipients:
Potassium:
This medicine contains 1/3 mmol potassium per 125mg. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
Sorbitol:
Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.
Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Aminoglycosides: Neomycin is reported to reduce the absorption of phenoxymethylpenicillin.

Anticoagulants: Penicillins may interfere with anticoagulant 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 Phenoxymethylpenicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity.

Probenecid: Reduced excretion of phenoxymethylpenicillin 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

Laboratory tests: Non enzymatic methods of detecting glucose in the urine may show false positive results during treatment with phenoxymethylpenicillin. Phenoxymethylpenicillin may also interfere with tests for urobilinogen.

4.6 Fertility, pregnancy and lactation

Fertility
Fertility data for phenoxymethylpenicillin are not available.

Pregnancy:
There are no or a limited amount of data from the use of Phenoxymethylpenicillin in pregnant women. As a precautionary measure, it is preferable to avoid the use of Phenoxymethylpenicillin during pregnancy.

Lactation:
Phenoxymethylpenicillin metabolites are excreted in human milk, presenting the risk of candidiasis and also of central nervous system toxicity due to prematurity of the blood brain barrier. There is a theoretical possibility of later sensitisation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The most common reactions to oral penicillin are gastrointestinal effects and hypersensitivity reactions. Hypersensitivity reactions of all intensities - to the point of anaphylactic shock- have also been observed after oral penicillin use. Severe anaphylactoid reactions, which occur significantly less often after oral administration of penicillin than after intravenous or intramuscular administration, may necessitate appropriate emergency management.

The following convention has been utilised for the classification of undesirable effects: -
Very common (≥1/10)
Common (≥1/100, <1/10)
Uncommon (≥1/1000, <1/100)
Rare (≥1/10,000, <1/1000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data).

Infections and infestations	Very rare	A pseudomembranous colitis may occur, mostly caused by Clostridioides difficile
Blood and lymphatic system disorders	Very rare	Changes in blood counts, including, thrombocytopenia, granulocytopenia, agranulocytosis neutropenia, leukopenia, Eosinophilia, pancytopenia and haemolytic anaemia. These changes are reversible on discontinuation. Coagulation disorders have also been reported.
Immune system disorders	Common	Allergic reactions (typically manifest as skin reactions). Urticarial, erythematous or mobilliform rash, pruritus may occur
	Very rare	Serious allergic reactions including drug fever, arthralgia, eosinophilia, angioedema, laryngeal oedema, bronchospasm, tachycardia, dyspnoea, serum sickness, hypersensitivity vasculitis and dropping of blood pressure up to life threatening shock. Frequently fever and eosinophilia will be the only manifestations of penicillin hypersensitivity.
Metabolism and Nutrition Disorders	Very common	Decreased appetite
Nervous system disorders	Rare	Taste disorder
	Not Known	Central nervous system toxicity including convulsions (especially with high doses or in severe renal impairment); paraesthesia may occur with prolonged use.
Gastrointestinal disorders	Common	Gastric discomfort, flatulence, nausea, vomiting, abdominal pain,

		diarrhoea, glossitis, stomatitis. These disorders are usually light and abate duringor at least after discontinuing treatment.
	Uncommon	Sore mouth and black hairy tongue (discolouration of tongue)
	Rare	Dry mouth
	Very rare	tooth discolouration
Hepatobiliary disorders	Rare	Transiently raised liver enzymes
	Very rare	Hepatitis and cholestatic jaundice
Skin and subcutaneous tissue disorders	Common	Rash
	Rare	Toxic epidermal necrolysis, Exfoliative dermatitis
	Very rare	Severe skin reactions such as Stevens-Johnson syndrome
Renal and urinary disorders	Very rare	Interstitial nephritis
Investigations	Rare	blood pressure decreased

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Ireland HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

4.9 Overdose

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.

Management: 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

Pharmacotherapeutic group: Anti-bacterials for systemic use, beta-lactamase sensitive natural penicillins, ATC Code: J01CE02.

Mechanism of Action:

Phenoxymethylpenicillin acts through interference with the final stage of synthesis of the bacterial cell wall. The action depends on its ability to bind certain membrane-bound proteins, (penicillin-binding proteins or PBPs) that are located beneath the cell wall. These proteins are involved in maintaining cell wall structure, in cell wall synthesis and in cell division, and appear to possess transpeptidase and carboxypeptidase activity.

Bacterial surface enzymes called autolysins also appear to be involved in the lethal effect of penicillins, particularly for gram-positive bacteria. In gram-negative bacilli osmotic rupture of cells may occur when the cell wall is weakened. Phenoxymethylpenicillin can also produce morphological changes in vitro including the formation of long filaments or abnormally shaped cells. Bacteria that are not growing or dividing are generally not killed by phenoxymethylpenicillin

PK/PD relationship

The time above the minimum inhibitory concentration (T>MIC) is considered to be the major determinant of efficacy for phenoxymethylpenicillin.

Mechanism(s) of Resistance:

The two main mechanisms of resistance to phenoxymethylpenicillin are:

- Inactivation by bacterial penicillinases and other beta-lactamases that are produced by certain microorganisms. The incidence of beta-lactamase producing organisms is increasing.
- Alteration of PBPs, which reduce the affinity of the antibacterial agent for the target.

Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance.

Susceptibility testing breakpoints MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for Phenoxymethylpenicillin and are listed here:

https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. Expert advice should be sought as necessary when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Commonly susceptible species
Streptococcus A, B, C,G
Species for which acquired resistance may be a problem
Staphylococcus aureus
Streptococcus pneumoniae
Staphylococcus epidermidis

5.2 Pharmacokinetic properties

Absorption: Rapidly but incompletely absorbed after oral administration (about 60% of an oral dose is absorbed). Calcium and potassium salts are better absorbed than the free acid. Absorption appears to be reduced in patients with coeliac disease. Absorption appears to be more rapid in fasting than non-fasting subjects.

Blood concentration: After an oral dose of 125mg, peak serum concentrations of 200 to 700ng/ml are attained in 2 hours. After an oral dose of 500mg, peak serum concentrations reach 3 to 5 micrograms/ml in 30 to 60 minutes.

Half-life: Biological half-life is about 30 minutes, increased to about 4 hours in severe renal impairment.

Distribution: Widely distributed throughout the body and enters pleural and ascitic fluids and also in cerebrospinal fluid when the meninges are inflamed; Phenoxymethylpenicillin crosses the placenta and is secreted in trace amounts in breast milk; (protein binding 50% to 80% bound plasma proteins).

Biotransformation: It is metabolised in the liver; several metabolites have been identified, including penicilloic acid.

Elimination: Unchanged drug and metabolites are excreted rapidly in the urine. (20% to 35% of an oral dose is excreted in the urine in 24 hours).

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

Sorbitol (E420)
Powdarome Strawberry Premium (Nature identical flavouring and natural flavouring, maize maltodextrin, INS1520 propylene glycol)
Sodium Saccharin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months.
The shelf life after reconstitution is 7 days.

6.4 Special precautions for storage

Store powder in a dry place below 25ºC

After reconstitution, phenoxymethylpenicillin Sugar Free oral solution must be stored between 2°C to 8°C and used within 7 days.

6.5 Nature and contents of container

150ml HDPE bottle with a 28mm child resistant cap. Each bottle contains 100 ml of reconstituted solution with a dosing syringe of 5ml.

6.6 Special precautions for disposal

No special requirements.
Add 86.0ml of water to the powder and shake vigorously. This will make 100ml of solution.
The solution should be used within 7 days of reconstitution.
Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Brown & Burk IR Limited
22 Northumberland Road
Ballsbridge
Dublin 4
Dublin
D04 ED73
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23148/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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