

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Phenoxymethylpenicillin Sugar Free Oral Solution BP 250 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of Oral Solution contains 250mg of Phenoxymethylpenicillin as Phenoxymethylpenicillin Potassium Ph. Eur.

3. PHARMACEUTICAL FORM

Powder for oral 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.

Note: Severe empyema, bacteraemia, pericarditis, meningitis and arthritis should not be treated with Penicillin V during the acute phase.

The following infections will usually respond to adequate doses:

Streptococcal infections (without bacteraemia): Mild to moderate infections of the upper respiratory tract, scarlet fever and mild erysipelas.

Pneumococcal infections: mild to moderately severe infections of the respiratory tract.

Staphylococcal infections sensitive to penicillin: mild infections of the skin and soft tissues.

Fusospirochetosis (Vincent's gingivitis and pharyngitis): mild to moderately severe infections of the oropharynx usually respond to therapy with oral penicillin.

Prophylactic use: prophylaxis with oral penicillin has proved effective in preventing recurrence of rheumatic fever and chorea.

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.

Note: oral penicillin should not be used as adjunctive prophylaxis for genito - urinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy and child birth.

4.2 Posology and Method of Administration

Dosage

Phenoxymethylpenicillin Sugar Free should be given in divided doses (3 to 4 times a day) and preferably half an hour before meals.

The following dosage schedule applies to Phenoxymethylpenicillin Sugar Free:

ADULTS AND CHILDREN OVER 5 YEARS; 125mg to 250mg every four to six hours.
The usual total daily dose is 500 to 1500mg in divided doses.

CHILDREN; 1 - 5 years: 125mg every six hours.
The usual total daily dosage is 500mg in divided doses.

INFANTS; (UP TO 1 YEAR): 62.5mg every six hours

ELDERLY: As for adults.

Prophylactic use: 250mg twice daily is recommended for long term prophylaxis of rheumatic fever

For oral administration only

4.3 Contra-indications

Phenoxymethylpenicillin is contraindicated in patients known to be hypersensitive to Penicillin and should be used with caution in patients with known histories of allergy.

4.4 Special Warnings and Special 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, cardiospasm 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.

4.5 Interaction with other Medicaments and Other Forms of Interaction

Guar gum: Reduced absorption of phenoxymethylpenicillin

Probenecid: Reduced excretion of phenoxymethylpenicillin by competing with it for renal tubular secretion.

Chloramphenicol, Erythromycin and Tetracyclines have been reported to antagonise the bactericidal activity of penicillins and concomitant use is not recommended.

Neomycin is reported to reduce the absorption of phenoxymethylpenicillin.

Penicillin may reduce the efficacy of combined oral contraceptives.

Use of Phenoxyethylpenicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity.

4.6 Pregnancy and Lactation

Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing to the pregnant patient. Phenoxyethylpenicillin is excreted in trace amounts in breast milk.

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 (including nausea, vomiting, abdominal pain and diarrhoea) and hypersensitivity reactions. Although 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.

The hypersensitivity reactions noted are skin eruptions (ranging from maculopapular to exfoliative dermatitis); urticaria; angioedema; reactions resembling serum sickness including interstitial nephritis, neutropenia, chills, fever, oedema, arthralgia and prostrationlaryngeal oedema and anaphylaxis; coagulation disorders (including prolongation of bleeding time and defective platelet function).

Central nervous system toxicity has been reported (especially with high doses or in severe renal impairment); paraesthesia may occur with prolonged use.

Other reactions observed with most oral antibiotics include antibiotic-associated colitis; a sore mouth and black hairy tongue have occasionally been reported.

Fever and eosinophilia may frequently be the only reactions observed.

Haemolytic anaemia, leucopenia, thrombocytopenia, neuropathy and nephropathy are infrequent reactions and are usually associated with high doses of parenteral penicillin.

4.9 Overdosage

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. PHARMACEUTICAL PARTICULARS

5.1 Pharmacodynamic Properties

In common with other penicillins, phenoxymethylpenicillin exerts its killing effects on growing and dividing bacteria by inhibition of bacterial cell wall synthesis. Phenoxymethylpenicillin has a similar range of activity to benzylpenicillin but may be less active against gram negative bacteria. Phenoxymethylpenicillin is used in the treatment of infections caused by susceptible staphylococci, pneumococci, gonococci, and haemolytic streptococci. Unless very large doses are given, phenoxymethylpenicillin administered by mouth is less effective than parenterally administered benzylpenicillin in the treatment of severe acute infections. It is inactivated by penicillinase.

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 5ug/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).

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

Excretion: 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

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium Benzoate Ph. Eur.
Saccharin Sodium Ph. Eur.
Trusil Orange Flavour HSE
Orange Colour 175 78 8 HSE
(Containing sunset yellow E110 & Ponceau 4R E124)
Sorbitol 60W
Mono Ammonium Glycyrrhizinate

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened container: 24 months
Reconstituted oral solution: a shelf life of 7 days

6.4 Special Precautions for Storage

Unconstituted powder: Store in a dry place below 25°C. Protect from light
Reconstituted oral solution: Store for 7 days in a refrigerator

6.5 Nature and Contents of Container

Natural high density polyethylene bottle with a polypropylene tamper evident or HDPE/polypropylene, tamper evident/ child resistant cap containing 100ml of oral solution on reconstitution.

May also contain

Hugo Meding – polypropylene spoon – Article number 7229
Or
5ml Medispoon
Or
A dosing syringe with bottle neck adaptor

6.6 Instructions for use/handling

No special instructions

7. Marketing Authorisation Holder

Athlone Laboratories Limited,
Ballymurray,
Co. Roscommon,
Ireland

8. Marketing Authorisation Number

PL 6453/0053

9. Date of First Authorisation/Renewal of Authorisation

1 December 1998

10. Date of Partial Revision of Text

11/11/2011