SCHEDULING STATUS:

S4

PROPRIETARY NAME (and dosage form)

BETAPEN TABLETS

COMPOSITION:

Each tablet contains phenoxymethylpenicillin potassium equivalent to 250mg (400 000 i.u.) of phenoxymethylpenicillin.

Contains Lactose monohydrate

PHARMACOLOGICAL CLASSIFICATION:

Category A.20.1.2. Penicillins.

PHARMACOLOGICAL ACTION:

Phenoxymethylpenicillin exerts a bactericidal action against penicillin sensitive micro-organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide. The drug exerts high in-vitro activity against staphylococci (except penicillinase-producing strains), streptococci (groups A,C,G,H,L and M) and pneumococci. Other organisms sensitive in-vitro to phenoxymethylpenicillin are Corynebacterium diphtheriae, Bacillus anthracis, Clostridia, Actinomyces bovis, Streptobacillus moniliformis, Listeria monocytogenes and Leptospira.

Phenoxymethylpenicillin has the distinct advantage over penicillin G in that it is resistant to inactivation by gastric acid. Absorption is variable. Once absorbed, phenoxymethylpenicillin is about 80% bound to serum protein.

Tissue levels are highest in the kidneys, with lesser amounts in the liver, skin and tissues. Small amounts are found in all other body tissues but it does not

readily enter the cerebrospinal fluid when the meninges are normal. The drug is excreted as readily

as it is absorbed in individuals with normal kidney function; however, recovery of the drug from the urine indicates that only about 25 % of the dosage given is absorbed. In neonates, young infants and individuals with impaired kidney function, excretion is considerably delayed.It is inactivated by penicillinase. It may be given with meals.

INDICATIONS

Phenoxymethylpenicillin is indicated in the treatment of mild to moderately severe infections due to penicillin G sensitive micro-organisms that are sensitive to the low serum levels obtained with this particular dosage form.

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

NOTE: Streptococci in groups A,C,H,G,L and M are very sensitive to penicillin. Other groups, including group D (enterococcus) are resistant.

Pneumococcal infections: Mild to moderately severe infections of the lungs.

Staphylococcal infections: Mild to moderate Penicillin G sensitive 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.

NOTE: Necessary dental care should be undertaken in infections involving the gums.

Medical conditions in which oral penicillin therapy is indicated as prophylaxis:

For the prevention of recurrence following rheumatic fever and / or chorea:

Prophylaxis with oral penicillin on a continuing basis has proven effective in preventing recurrence of these conditions.

Patients who have a past history of rheumatic fever and are receiving continuous prophylaxis may harbour increased numbers of penicillin resistant organisms; use of another prophylactic anti-infective agent should be considered.

CONTRA-INDICATIONS:

Must not be administered to patients who are allergic to penicillin and not in the neonatal period, to babies born of hypersensitive mothers. Has no action on penicillinase-producing strains. Severe pneumonia, empyema, bacteremia, pericarditis, meningitis and arthritis should not be treated with phenoxymethylpenicillin during the acute stage.

DOSAGE AND DIRECTIONS FOR USE:

The dosage of phenoxymethylpenicillin should be determined according to the sensitivity of the causative micro-organisms and the severity of the infection,and adjusted to the clinical response of the patient.

As blood levels are slightly higher if given on an empty stomach, the dose should be taken about half an hour before meals.

The usual dosage recommendations for adults and children over 12 years are as follows:

Streptococcal infections - mild to moderately severe, of the upper respiratory tract, including scarlet fever and erysipelas: 125mg - 500mg every 6-8 hours for 10 days.

Pheumococcal infections - mild to moderately severe, of the respiratory tract, including otitis media, 250mg - 500mg every 6 hours until the patient has been afebrile for at least two days.

Staphylococcal infections - mild infections of the skin and soft tissue (culture and sensitivity tests should be performed): 250mg - 500mg every 6 - 8 hours.

Fusospirochetosis (Vincent's infection) of the oropharynx. Mild to moderately severe infections: 250mg - 500mg every 6-8 hours.

For the prevention of recurrence following rheumatic fever and / or chorea: 125mg - 250 mg twice daily on a continuing basis.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Must not be administered to a patient with a history of hypersensitivity to penicillin. Caution must be exercised when treating individuals with a history of allergy and / or asthma. The incidence of allergic reactions to oral penicillin is less than that encountered with parenteral therapy but all degrees of hypersensitivity, including fatal anaphylaxis, have been reported. The treatment of allergic symptoms consists of immediate cessation of treatment and the administration of antihistamines or corticosteroids. Anaphylaxis is treated with adrenalin, corticosteroids and aminophyllin.

The reactions most commonly reported are nausea, vomiting, epigastric distress, diarrhoea and black hairy tongue. They are usually transient and can be controlled by withdrawal of treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Any form of actual toxicity of phenoxymethylpenicillin is rare and doses of 8 g have been well tolerated. However in patients with renal impairment dosage may be reduced if required

IDENTIFICATION

White to off-white, round, biconvex tablet, with a diameter of 9,50mm, and a score on the one side.

PRESENTATION

Containers of 20, 100, 500, 1000 and 5000 tablets.

Patient ready packs of different pack sizes.

STORAGE INSTRUCTIONS:

Store under cool, dry conditions (at or below 25^{o}C). Protect from light.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS:

L /20.1.1/184 (S.A)

B9314850 (Botswana)

POM168/003 (Zambia) 1000's

NS2 90/20.1.1/00368 (Namibia)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

RANBAXY PHARMACEUTICALS (PTY) LTD

14 LAUTRE ROAD

STORMILL, EXT. 1

ROODEPOORT

1724

SOUTH AFRICA

DATE OF PUBLICATION OF THIS PACKAGE INSERT

13 SEPTEMBER 2019

DATE ON THE REGISTRATION CERTIFICATE OF THE MEDICINE

16 JANUARY 1980