Penicillin V Potassium Tablets 250mg/500mg Taj Pharma

1. NAME OF THE MEDICINAL PRODUCT

Penicillin V Potassium Tablets 250mg Taj Pharma
Penicillin V Potassium Tablets 500mg Taj Pharma

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

a) Penicillin V Potassium Tablets 250mg
Each film coated tablet contains:
Penicillin V Potassium USP
Equivalent to Phenoxymethylpenicillin potassium 250mg
Excipients: Q.S.

b) Penicillin V Potassium Tablets 500mg
Each film coated tablet contains:
Penicillin V Potassium USP
Equivalent to Phenoxymethylpenicillin potassium 500mg
Excipients: Q.S.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in the treatment of mild to moderately severe infections caused by penicillin sensitive organisms.

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

4.2 Posology and method of administration

Posology

Adults: The dosage is 250-500mg every six hours.

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

Prophylactic Use: The dosage is 250mg daily for long term prophylaxis of rheumatic fever.

Paediatric population

Children 1-5 years: 125mg every six hours

6-12 years: 250mg every six hours

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

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.

Method of administration

Penicillin VK Tablets 250mg/Phenoxymethylpenicillin Taj Pharma 250mg Film-Coated Tablets are for oral use.

Each tablet should be swallowed whole with water, at least 30 minutes before food, as ingestion of Phenoxymethylpenicillin Taj Pharma with meals slightly reduces the absorption of the drug.

4.3 Contraindications

Phenoxymethylpenicillin Taj Pharma is contraindicated in patients with known 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 Taj Pharma.

4.4 Special warnings and precautions for use

Phenoxymethylpenicillin Taj Pharma should be given with caution to patients with a history of allergy, especially to other drugs. Phenoxymethylpenicillin Taj Pharma should also be given cautiously to cephalosporin-sensitive patients, as there is some evidence of partial cross-allergenicity between the cephalosporins and penicillins. Patients have had severe reactions (including anaphylaxis) to both drugs. If the patient experiences an allergic reaction Phenoxymethylpenicillin Taj Pharma should be discontinued and treatment with the appropriate agents initiated (e.g. adrenaline and other pressor amines, antihistamines and other corticosteroids).

Particular caution should be exercised in prescribing Phenoxymethylpenicillin Taj Pharma to patients with an allergic diathesis or with bronchial asthma

Oral penicillins are not indicated in patients with severe illness or with a gastrointestinal disease that causes persistent nausea, vomiting gastric dilation, cardiospasm, intestinal hypermotility or diarrhoea because absorption may be reduced. Occasionally, patients do not absorb therapeutic amounts of orally administered penicillin.

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.

In patients undergoing long-term Phenoxymethylpenicillin Taj Pharma treatment the complete and differential blood count, as well as the liver and kidney function, should be monitored.

During long-term treatment attention should also be paid to the potential overgrowth of resistant organisms including Pseudomonas or Candida. If super-infection occurs, appropriate measures should be taken.

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

Each tablet of Penicillin VK Tablets 250mg/Phenoxymethylpenicillin Taj Pharma 250mg Film-Coated Tablets contains 28mg 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.

In renal impairment the safe dosage may be lower than usually recommended.

During treatment with Phenoxymethylpenicillin Taj Pharma non-enzymatic glucose tests may be false-positive.

4.5 Interaction with other medicinal products and other forms of interaction

As penicillins like Phenoxymethylpenicillin Taj Pharma are only active against proliferating microorganisms, Phenoxymethylpenicillin Taj Pharma should not be combined with bacteriostatic antibiotics such as tetracycline, erythromycin, chloramphenicol and sulphonamides.

Concomitant use of uricosuric drugs (e.g. probenecid and sulfinpyrazone) reduces the excretion of Phenoxymethylpenicillin Taj Pharma resulting in increased plasma levels and thus prolongs its action.

Phenoxymethylpenicillin Taj Pharma may reduce the excretion of methotrexate causing an increased risk of toxicity.

During treatment with Phenoxymethylpenicillin Taj Pharma non-enzymatic urinary glucose tests may be false-positive.

Guar gum may slow the speed of absorption of Phenoxymethylpenicillin Taj Pharma.

Phenoxymethylpenicillin Taj Pharma has the following interaction information:

Neomycin - absorption of Phenoxymethylpenicillin Taj Pharma reduced by neomycin.

Combined use of Phenoxymethylpenicillin Taj Pharma and oral anticoagulants (e.g. warfarin) may prolong prothrombin time.

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.

Thyphoid Vaccines – antibacterials inactive oral typhoid vaccine.

4.6 Pregnancy and lactation

Pregnancy

Animal studies with Phenoxymethylpenicillin Taj Pharma potassium have shown no teratogenic effects.

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

Lactation

Breast feeding is not contraindicated with Phenoxymethylpenicillin Taj Pharma potassium. Trace quantities of Phenoxymethylpenicillin Taj Pharma 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

Potential allergic reactions include urticaria, angioneurotic oedema, erythema multiforme, exfoliative dermatitis, fever, joint pain, serum sickness-like reactions, haemolytic anaemia, interstitial nephritis or anaphylactic shock (which could be fatal) with collapse and anaphylactoid reactions (asthma, purpura, gastrointestinal symptoms). Although these are less common, and take a milder course, in oral treatment than during parenteral penicillin treatment, it should be remembered that all degrees of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin.

Gastro-intestinal tract

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

Nausea, diarrhoea, vomiting, stomatitis and glossitis are sometimes seen.

Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis. As this condition may be life-threatening Phenoxymethylpenicillin Taj Pharma should be withdrawn immediately and treatment guided by bacteriologic studies with appropriate antibiotherapy (i.e. vancomycin)..

Blood

Eosinophilia, haemolytic anaemia, leukopenia, thrombocytopenia and agranulocytosis are extremely rare. Other possible effects on the

blood composition include: neutropenia, 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.

As with other broad-spectrum antibiotics prolonged use may result in the overgrowth of non-susceptible organisms, e.g. candida. This may present a vulvo-vaginitis.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Overdose

A large overdose may cause nausea, vomiting and diarrhoea. Rarely major motor seizures may occur. There is no known antidote. Symptomatic and supportive therapy is recommended. It is advisable to monitor blood levels in patients with renal malfunction.
Phenoxymethylpenicillin Taj Pharma may be removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Phenoxymethylpenicillin Taj Pharma is a broad spectrum 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 Taj Pharma is usually active against the following organisms:

Gram-positive aerobes and anaerobes including

Bacillus anthracis
Clostridium perfringens
Clostridium tetani
Corynebacterium diphtheria
Erysipelothrix rhusiopathiae
Listeria monocytogenes
Peptostreptococcus spp.
Streptococcus agalactiae (Group *B)*
Streptococcus pneumonia
Streptococcus pyogenes (Group *A)*

Gram-negative including

Neisseria meningitides
Neisseria gonorrhoeae

Phenoxymethylpenicillin Taj Pharma is inactivated by penicillinase and other beta-lactamases.

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

5.2 Pharmacokinetic properties

Absorption

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

Phenoxymethylpenicillin Taj Pharma 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 Taj Pharma, 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. Peak serum concentrations of 3-6 jig per ml have been seen following dosage of 250mg to 500mg by mouth.

Distribution

Phenoxymethylpenicillin Taj Pharma is widely distributed round the body tissues and fluids

(volume of distribution about 0.2 1 kg-1 of body weight) and more readily penetrates inflamed tissues. It also diffuses across the placenta into foetal circulation and small amounts appear in the milk of nursing mothers. Eighty per cent is reported to be protein bound.

Biotransformation

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

Elimination

The plasma half-life of Phenoxymethylpenicillin Taj Pharma is about 45 minutes which may increase to four hours in renal failure.

Excretion is by tubular secretion into urine. 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. Small excretion occurs in bile.

Impaired absorption is seen in patients with coeliac disease.

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

Tablet core:
Magnesium stearate, Talc Macrogol 6000, Povidone, Maltodextrin, Tablet coating, Titanium dioxide, Hypromellose, Talc

Incompatibilities

There are no known incompatibilities.

6.2 Shelf life

This medicinal product as packaged for sale has a shelf life of two years.

6.3 Special precautions for storage

The following applies to the storage of Penicillin VK Tablets 250mg/Phenoxymethylpenicillin Taj Pharma 250mg Film-Coated Tablets:

- “Do not store above 25°C”
- 'Store in the original packaging” (when packaged in blisters)
- 'Keep the container tightly closed” (when packaged in securitainers)

6.4 Nature and contents of container

The 250mg film coated tablets are presented in the following containers

- Amber glass bottles with polyethylene twist off closures containing 50 or 100 tablets.
- Polypropylene containers with polyethylene snap on caps containing 50, 500 or 1000 tablets.
- Blister strips of 10, 14, 20, 21, 28, 30, 100 tablets.

Not all pack sizes may be marketed.

6.5 Special precautions for disposal and other handling

No special requirements.

Manufactured in India by:
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