Approved Professional Information for Medicines for Human Use: DEZZPEN 250

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

DEZZPEN 250 tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DEZZPEN 250 tablets

Each tablet contains phenoxymethylpenicillin potassium equivalent to 250 mg phenoxymethylpenicillin.

Contains sugar: lactose monohydrate 52 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral

DEZZPEN 250 tablets

Shiny, white, flat tablet with break line on the one side and plain on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DEZZPEN 250 is used for the treatment of mild to moderate infections caused by sensitive organisms: Pneumococcal infections of the middle ear, Streptococcal otitis media and sinusitis, Streptococcal pharyngitis caused by Streptococcus pyogenes, mild to moderate pulmonary and periodontal anaerobic infections, gingivostomatitis, early Lyme disease.

Prophylactic: Recurrence of rheumatic fever.

4.2 Posology and method of administration

Posology

Prophylactic use: 125 - 250 mg twice a day.

Adult therapeutic dose: 250 mg - 500 mg every six hours, depending on the severity of the infection.

Streptococcal pharyngitis must be treated for a minimum of 10 days.

Method of administration

DEZZPEN 250 should be taken 1 hour before or at least 2 hours after meals.

4.3 Contraindications

- Hypersensitivity to phenoxymethylpenicillin, other penicillins, betalactam antibiotics, or to any of the excipients listed in section 6.1. It should be given with care to patients with a history of allergy to cephalosporins as cases of cross sensitivity have been reported.
- Babies, in the neonatal period, born of hypersensitive mothers.
- Chronic, severe or deep-seated infections such as subacute bacterial endocarditis, meningitis or syphilis.

4.4 Special warnings and precautions for use

Penicillin sensitivity and serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous reactions) may occur with administration of DEZZPEN 250. Epinephrine (adrenaline), corticosteroids and antihistamines should be used to treat anaphylaxis. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8). These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin therapy must be discontinued, and appropriate alternative therapy instituted.

DEZZPEN 250 should be used with caution in persons with a history of allergies especially to

medicines. Late reactions of hypersensitivity may include serum sickness-like reactions and haemolytic anaemia.

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.

Superinfection by resistant species, such as Pseudomonas, Candida, or Clostridium difficile which do not respond to penicillin therapy, may occur.
Care should be taken when treating patients with syphilis, as the Jarisch-Herxheimer reaction may occur shortly after initiating treatment. This reaction, manifesting as fever, chills, headache and reactions at the site of the lesion, can be dangerous in cardiovascular syphilis or where there is a serious risk of increased local damage such as with optic atrophy.

Oral therapy should not be relied upon in patients with severe illness, or with nausea, vomiting, gastric dilation, cardio spasm or intestinal hypermotility.
Occasionally, patients do not absorb therapeutic amounts of orally administered penicillin.

Care should be taken when high doses are given to patients with renal impairment (because of the risk of neurotoxicity) or congestive heart failure.
Renal and haematological systems should be monitored during prolonged and high dose therapy.
Convulsions and other signs of toxicity to the CNS may occur particularly in patients with renal failure.

Skin contact with penicillins should be avoided since sensitisation may occur. Disturbances of blood electrolytes may follow the administrations of large doses of DEZZPEN 250. High doses should be used with caution in patients receiving potassium containing medicines or potassium-sparing diuretics, especially in patients with renal impairment or heart failure.

During treatment with phenoxymethylpenicillin non-enzymatic glucose tests may be false-positive.

Excipient lactose

DEZZPEN 250 contains lactose. It should be administered with caution to patients with rare heredity problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption.

4.5 Interaction with other medicines and other forms of interaction

Probenecid prolongs the half-life of phenoxymethylpenicillin (in DEZZPEN 250) by competing with it for renal tubular excretion.

Phenoxymethylpenicillin reduces the excretion of cytotoxic medicine, methotrexate.

Avoid concomitant administration with bacteriostatic antimicrobials such as erythromycin, chloramphenicol~~, and~~ tetracyclines and sulphonamides because it can diminish the effect of phenoxymethylpenicillin potassium.

In case of simultaneous administration of phenoxymethylpenicillin and oral contraceptives, the hormonal contraception can lose its efficacy. Patients should be advised to use additional forms of contraceptives precautions while taking phenoxymethylpenicillin.

Guar gum may reduce the absorption of phenoxymethylpenicillin in DEZZPEN 250.

Reduced absorption has also been reported when phenoxymethylpenicillin such as in DEZZPEN 250 was given following a course of aminoglycosides such as neomycin by mouth.

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 - penicillin may inactivate oral typhoid vaccine.

Interaction with laboratory tests:

DEZZPEN 250 may interfere with some diagnostic tests such as those for urinary glucose using copper sulphate, direct antiglobulin (Coombs') tests, and some tests for urinary or serum proteins. It may also interfere with tests that use bacteria, for example the Guthrie test for phenylketonuria using Bacillus subtilis organisms.

4.6 Fertility, 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 trials. However, as with other medicines, caution should be exercised when prescribing to pregnant patients.

Breastfeeding

Breastfeeding 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

Patients should be warned to be cautious until they know how DEZZPEN 250 will affect their ability to drive or use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and post-marketing spontaneous reports with phenoxymethylpenicillin.

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Blood and lymphatic system disorders			Neutropenia, haemolytic anaemia, leukopenia, thrombocytopenia, agranulocytosis, prolongation of bleeding time and defective platelet function
Immune system disorders			Allergic reactions which may include anaphylaxis, angioedema, erythema multiforme, exfoliative dermatitis, maculopapular rashes, other skin rashes and vasculitis
Metabolism and nutrition disorders			Sore mouth and a black hairy tongue
Nervous system disorders			Convulsions and other central nervous system toxicities
Cardiac disorders			Kounis syndrome

Skin and subcutaneous tissue disorders			Linear IgA disease
Gastrointestinal disorders			Diarrhoea, nausea, heartburn, stomatitis, glossitis. 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 with appropriate antibiotic therapy (i.e. vancomycin)
Hepatobiliary disorders			Increase in liver enzyme values
Renal and urinary disorders			Neuropathy and interstitial nephritis
Reproductive system disorders			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.
General disorders			A generalised sensitivity reaction with urticaria, fever, joint pains and eosinophilia can develop within a few hours to several

			weeks after starting treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via medsafety@shanur.co.za.

4.9 Overdose

Treatment is symptomatic and supportive.

It is advisable to monitor blood levels in patients with renal malfunction.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 20.1.2 Penicillins

Pharmacotherapeutic group: Beta lactamase sensitive penicillins

ATC Code: J01CE02

Mechanism of action

Phenoxymethylpenicillin is a narrow spectrum penicillin, inhibited by penicillinase. It has an antimicrobial spectrum similar to benzylpenicillin for aerobic Gram+ organisms. Organisms that may be resistant to phenoxymethylpenicillin are: *Viridans streptococci, S. pneumonia, S. aureus, S. epidermidis, Gonococci, Corynebacterium diphtheria, Bacteroides fragilis, Prevotella melaninogenicus*. None of the penicillins is effective against amoebae, plasmodia, rickettsiae, fungi or viruses.

5.2 Pharmacokinetic properties

It is stable in acidic medium and is therefore absorbed from the gastro-intestinal tract. Absorption is usually good, although variable, about 60 % of an oral dose being absorbed. The plasma half-life of phenoxymethylpenicillin is about 30 to 60 minutes and may be increased to about 4 hours in severe renal impairment. About 80 % is reported to be protein bound. Phenoxymethylpenicillin is metabolised in the liver and the unchanged phenoxymethylpenicillin and metabolites are excreted rapidly in the urine. Only small concentrations are excreted in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Maize starch

Magnesium stearate

Pregelatinised starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 °C. Store in a cool, dry place.

Keep the container well closed.

Keep the blisters packs in the outer carton until required for use.

6.5 Nature and contents of container

DEZZPEN 250 tablets

HDPE container:

Packed in a transparent polypropylene bag, which is then sealed. The sealed bag is packed into a white, round HDPE container together with the package insert & a desiccant (silica bag).

The HDPE container is sealed with a plain aluminium tagger and is then capped with a white screw type HDPE lid.

Pack sizes: 40, 100 & 1 000 tablets.

Blister packs:

Aluminium foil and clear PVDC blisters containing 10 tablets. Four or ten blister strips are packed in an

outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

DEZZPEN 250 tablets: 45/20.1.2/0348

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 July 2016

10. DATE OF REVISION OF THE TEXT

13 March 2026