

Approved Patient Information Leaflet for Medicines for Human Use: DEZZPEN 250

SCHEDULING STATUS: S4

DEZZPEN 250 tablets

Phenoxymethylpenicillin (as the potassium salt)

Contains sugar: lactose monohydrate.

Each tablet contains 52 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking DEZZPEN 250

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other health care provider.
- DEZZPEN 250 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DEZZPEN 250 is and what it is used for
2. What you need to know before you take DEZZPEN 250
3. How to take DEZZPEN 250
4. Possible side effects
5. How to store DEZZPEN 250
6. Contents of the pack and other information

1. What DEZZPEN 250 is and what it is used for

DEZZPEN 250 belong to a family of medicines called antibiotics, in a group called 'penicillins'

DEZZPEN 250 is used to treat infections caused by bacteria that are sensitive to phenoxymethylpenicillin. These infections include:

- infections of the middle ear (such as otitis media)
- sinus and throat infections (such as sinusitis and pharyngitis)

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- mild to moderate lung infections
- early Lyme disease.

It is also used to prevent recurrent attacks of rheumatic fever.

2. What you need to know before you take DEZZPEN 250

Do not take DEZZPEN 250

- If you are allergic (hypersensitive) to penicillin or cephalosporins or any of the other ingredients of DEZZPEN 250 (listed in section 6).
- In babies, in the neonatal period, whose mothers are allergic to penicillin.
- For chronic, severe or deep-seated infections such as a bacterial infection of the lining of the heart (subacute bacterial endocarditis), inflammation of the protective membranes covering the brain or spinal cord (meningitis) or the sexually transmitted disease, syphilis.

Warnings and precautions

Take special care with DEZZPEN 250

- if you have a history of allergies, DEZZPEN 250 can cause allergic reactions, including life-threatening shock.
- as some bacteria may be resistant to DEZZPEN 250 and can cause you to develop a superinfection.
- if you are being treated for syphilis, as DEZZPEN 250 can cause symptoms such as fever, chills, increased heart rate, or skin lesions (Jarisch-Herxheimer reaction).
- if you have a severe illness.
- if you have persistent diarrhoea, are feeling or being sick, or are suffering from any gut disorder which may affect the way your body absorbs the medicine.
- if you have kidney problems because DEZZPEN 250 can cause nerve problems if you have a kidney condition.
- if you have heart failure.
- if you require prolonged treatment with high doses, your doctor may need to monitor certain

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functions, such as your blood and kidney function.

- by avoiding skin contact, as this may cause you to develop an allergy to DEZZPEN 250.
- if you are taking medicines containing potassium or potassium-sparing diuretics.
- if you have your urine tested for glucose using a non-enzymatic test, then DEZZPEN 250 may give a false positive result.

Other medicines and DEZZPEN 250

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- other antibiotics such as tetracyclines, erythromycin, sulphonamide and chloramphenicol
- guar gum to lower blood sugar levels
- neomycin to treat bacterial infections
- probenecid to treat pain and swelling of the joints and sulfinpyrazone to lower blood uric acid levels (gout)
- methotrexate (a medicine used to treat cancer, psoriasis and rheumatoid arthritis)
- the contraceptive pill, as phenoxymethylpenicillin potassium may reduce the effect of the pill, you should therefore take extra contraceptive precautions while taking this medicine.

DEZZPEN 250 can also affect some diagnostic tests, such as diabetic tests for sugar (glucose).

Please tell your doctor or pharmacist if you have recently been given or are due to receive a typhoid vaccination.

Taking DEZZPEN 250 with food and drink

These tablets should be taken with water either an hour before, or two hours after a meal.

Pregnancy and breastfeeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DEZZPEN 250.

Driving and using machines

It is not always possible to predict to what extent DEZZPEN 250 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DEZZPEN 250 affects them.

If you are feeling dizzy, drowsy or unwell you should avoid driving or using machinery.

DEZZPEN 250 contains lactose

DEZZPEN 250 contains lactose which may affect you if you are lactose intolerant, suffer from a heredity galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

3. How to take DEZZPEN 250

Do not share medicines prescribed for you with any other person.

Always take DEZZPEN 250 exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

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.

Duration of administration

Your doctor will prescribe an appropriate dose according to your condition.

Your doctor will tell you how long your treatment with DEZZPEN 250 will last. Do not stop treatment early as your infection may come back or get worse.

Method of administration

The usual way to take DEZZPEN 250 is as follows:

Take 1 hour before or at least 2 hours after meals.

If you take more DEZZPEN 250 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DEZZPEN 250

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DEZZPEN 250 can have side effects.

Not all side effects reported for DEZZPEN 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DEZZPEN 250, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking DEZZPEN 250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden wheezing, swelling of your lips, tongue and throat or body, difficulties in swallowing (severe allergic reaction)
- rash or itching
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin but can affect other parts of the body
- reddening of the skin with blisters or peeling

- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to DEZZPEN 250. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe skin rashes
- various forms of anaemia (reduction in red blood cells) causing pale skin, weakness, or breathlessness
- other blood disorders causing excessive bleeding (including blood in your urine or stools), bruising, sore throat, general illness or fever
- convulsions (fits)
- less urine than is normal for you
- diarrhoea (especially if persistent and severe)
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- sore mouth
- black tongue which looks hairy
- feeling sick (nausea) or vomiting
- heartburn
- rash with blisters arranged in a circle with central crusting or like a string of pearls (leishmaniasis or discharge from the vagina. near IgA disease)
- thrush or discharge from the vagina.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DEZZPEN 250.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za.

5. How to store DEZZPEN 250

Store all medicines out of reach of children.

- 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.
- Do not use this medicine after the expiry date.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEZZPEN 250 contains

The active substance is phenoxymethylpenicillin (as the potassium salt).

The other ingredients are lactose monohydrate, magnesium stearate, maize starch and pregelatinized starch.

DEZZPEN 250 tablets

Each tablet contains phenoxymethylpenicillin potassium equivalent to 250 mg phenoxymethylpenicillin.

What DEZZPEN 250 looks like and contents of the pack

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

HDPE container:

DEZZPEN 250 tablets are 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:

DEZZPEN 250 tablets are packed into foil and clear plastic blister strips containing 10 tablets. Four or ten blister strips are packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd

Loch House Unit 003

3A/5 Eton Road, Parktown

Johannesburg, 2193

Tel: +27 87 405 9660

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DEZZPEN 250 tablets: 45/20.1.2/0348

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: <https://shanur.co.za/product-info/>

Shanur Healthcare (Pty) Ltd

Tel: +27 87 405 9660