

Approved Patient Information Leaflet for Medicines for Human Use:

METPEN 125/250

SCHEDULING STATUS: S4

METPEN 125 powder for oral solution

Phenoxymethylpenicillin potassium

Contains sugar (castor grade): 2610,00 mg

Contains sweetener: Saccharin sodium: 0,50 mg

METPEN 250 powder for oral solution

Phenoxymethylpenicillin potassium

Contains sugar (castor grade): 2550,00 mg

Contains sweetener: Saccharin sodium: 1,0 mg

Read all of this leaflet carefully before you start taking METPEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- METPEN 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 METPEN is and what it is used for
2. What you need to know before you take METPEN
3. How to take METPEN

4. Possible side effects

5. How to store METPEN

6. Contents of the pack and other information

1. What METPEN is and what it is used for

The name of your medicine is METPEN 125 mg/5 mL and 250 mg/5 mL Powder for oral solution.

It is available in two strengths as powder for reconstitution. The powder for reconstitution is prepared by the pharmacist before dispensing by adding water to the powder to give 100 ml of oral solution. The strength you are given will be decided by your doctor

METPEN contains the active substance called Phenoxyethylpenicillin potassium which belongs to the group of medicines called penicillins, which are used to kill bacteria that cause infections in your body.

METPEN is used to:

- treat bacterial infections of the ear, throat, respiratory tract, skin and soft tissues
- prevent infections such as rheumatic fever or chorea (an abnormal involuntary movement disorder) recurring

2. What you need to know before you take METPEN

Do not take METPEN

- if you are hypersensitive (allergic) to phenoxyethylpenicillin potassium, cephalosporin or any of the other ingredients of METPEN (listed in section 6).
- if you have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

Warnings and precautions

Take special care with METPEN

- If you suffer from any stomach problems e.g. vomiting
- If you suffer from any kidney problems

- If you suffer from allergies and/or asthma

Other medicines and METPEN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Anticoagulants (medicines that prevent clotting of blood),
- Methotrexate (medicine used to treat cancer and psoriasis)
- Sulfinpyrazone or Probenecid (medicines used to treat gout)
- Oral Typhoid vaccine (penicillin can stop this working)
- Chloramphenicol and Tetracyclines (broad spectrum antibiotics).
- Neomycin which can result in decreased absorption of METPEN.

Pregnancy, breastfeeding and fertility

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 METPEN.

Driving and using machines

It is not always possible to predict to what extent METPEN 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 METPEN affects them.

3. How to take METPEN

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

Always take METPEN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

(1) Streptococcal infections:

Adults: 125 to 250 mg every 4 hours

Children: upto 1 year 60 mg every 6 hours

1 to 5 years: 125 mg every 6 hours

6 to 12 years: 250 mg every 6 hours

(2) Rheumatic fever prophylaxis: 125 mg every 12 hours.

Direction for reconstituting; 100 mL syrup. Add 65 mL water and shake well to dissolve. Shake the bottle well before use.

Duration of administration

Your doctor will tell you how long your treatment with METPEN.

Method of administration

Shake the bottle well before use.

If you take more METPEN 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 METPEN

Do not take a double dose to make up for forgotten individual doses.

If you stop taking METPEN

Do not stop treatment early because if you feel better. If you have the impression that the effect of METPEN is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects

METPEN can have side effects.

Not all side effects reported for METPEN are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other health care provider for advice.

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

- An allergic reaction- symptoms may include: shortness of breath, skin rash or itching, hives, swelling of the skin (especially of the lips, face or tongue), chills or fever, painful joints,
- severe peeling/blistering of the skin,
- serum sickness-like reactions (characterised by fever, chills, joint pains and oedema),
- seizures,
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- pins and needles or numbness

- nausea, vomiting

Less frequent side effects:

- infections or fever (may be caused by low white blood cells)
- anaemia (may cause lack of energy or tiredness)
jaundice (yellowing of skin or whites of the eyes)
- kidney problems, which might cause blood in the urine or reduced amounts of urine

Side effects with frequency unknown:

- problems with blood clotting (unusual bleeding or bruising)
- sore mouth
- sore throat
- black hairy tongue
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered heart disease (Kounis syndrome)

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 or nurse. 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 METPEN.

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

5. How to store METPEN

Store all medicines out of reach of children.

Unconstituted powder: Store in a dry place at or below 25 °C.

Reconstituted oral solution: Store for 7 days in a refrigerator.

Do not use after the expiry date stated on the label

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 METPEN contains

- The active substance is phenoxymethylpenicillin potassium.
- The other ingredients are: sucrose (castor grade), strawberry flavour 17.41.05, red dye (Anstead) 1578 E124 and sodium saccharin,

METPEN 125 powder for oral solution

Each 5 mL after reconstitution contains phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 125 mg.

METPEN 250 powder for oral solution

Each 5 mL after reconstitution contains phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 250 mg.

What METPEN looks like and contents of the pack

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Austell Laboratories (Pty) Ltd, 420038-39, METPEN 125/250, Powder for oral solution, 125 mg and 250 mg

METPEN 125/250 is a light pink powder with an odour of strawberry, when reconstituted, a clear pink solution is obtained.

White-Opaque HDPE bottle of 100 ml, with a tamper evident cap.

Holder of Certificate of Registration

Austell Laboratories (Pty) Ltd,

52 Mineral Crescent,

Crown ext 3,

Johannesburg, 2092,

South Africa

This leaflet was last revised in

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METPEN 125: 42/20.1.2/0038

METPEN 250: 42/20.1.2/0039

Access to the corresponding Professional Information and Afrikaans Patient

Information Leaflet

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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