Patient Information Leaflet

SCHEDULING STATUS

S4

BETAPEN 125 mg GRANULES

Phenoxymethylpenicillin potassium

Sugar 2,5 g

BETAPEN 250 mg GRANULES

Phenoxymethylpenicillin potassium

Sugar 2,3 g

Read all of this leaflet carefully before you start taking BETAPEN GRANULES

- 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.
- BETAPEN GRANULES 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 the leaflet

1. What BETAPEN 125 mg/250 mg GRANULES is and what it is used for
2. What you need to know before you take BETAPEN 125 mg/250 mg GRANULES
3. How to take BETAPEN 125 mg/250 mg GRANULES
4. Possible side effects
5. How to store BETAPEN 125 mg/250 mg GRANULES
6. Contents of the pack and other information

1. What BETAPEN GRANULES is and what it is used for

The name of your medicine is BETAPEN 125 mg GRANULES or BETAPEN 250 mg GRANULES

BETAPEN 125 mg GRANULES and BETAPEN 250 mg GRANULES contains. It is available in two strengths as a 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 granules for suspension. The strength you are given will be decided by your doctor.

Phenoxymethylpenicillin, the active ingredient, is an antibiotic, which belongs to group of medicines called penicillins, which are used to kill bacteria that cause infections in your body.

Your medicine is used to:

- treat bacterial infections of the ear, throat, respiratory tract, skin and soft tissues
- prevent infections such as rheumatic fever.

2. What you need to know before you take

BETAPEN GRANULES

Do not take BETAPEN GRANULES if:

You ever had a bad reaction or allergic reaction to any Phenoxymethylpenicillin or Cephalosporin-type antibiotic. An example of a Cephalosporin-type antibiotic is Cefradine.

You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

You are allergic (hypersensitive) to phenoxymethylpenicillin or any of then other ingredients of this medicine (listed in Section 6)

Warnings and precautions

Take special care with BETAPEN GRANULES

- 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
- if you have a serious allergic reaction that could lead to heart problems.

Other medicines and BETAPEN GRANULES

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

Methotrexate (a drug used to treat cancers and psoriasis)

Anticoagulants {e.g. warfarin - to prevent blood clots)

Sulfinpyrazone or Probenecid (medicines used to treat gout)

Oral Typhoid vaccine (penicillin can stop this from working)

Some other antibiotics (Tetracycline, Erythromycin, Chloramphenicol, and Neomycin)

BETAPEN GRANULES with food and drink

Take your medicine on an empty stomach either half an hour before a meal or at least three hours after a meal. Your doctor will advise you about this.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, 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 this medicine.

Driving and using machines

This medicine should not affect your ability to drive or to use machinery.

3. How to take BETAPEN GRANULES

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

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

1) **Streptococcal infections:**

Adults: 125 to 250 mg every 4 hours

Children: up to 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.

FOR BETAPEN 125 mg GRANULES:

DIRECTIONS FOR RECONSTITUTING 100 ml SUSPENSION

Add 69 ml of water in divided amounts shaking after each addition.

DIRECTIONS FOR RECONSTITUTING 60 ml SUSPENSION

Add 41,5 ml of water in divided amounts shaking after each addition.

FOR BETAPEN 250 mg GRANULES:

DIRECTIONS FOR RECONSTITUTING 100 ml SUSPENSION

Add 68 ml of water in divided amounts shaking after each addition.

If you take more BETAPEN GRANULES 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 BETAPEN GRANULES

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking BETAPEN GRANULES

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

BETAPEN GRANULES can have side effects.

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

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

If any of the following happens, stop taking / using BETAPEN GRANULES 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 all very serious side effects. If you have them, you may have had a serious reaction to BETAPEN GRANULES. 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:

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea

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

Tell your doctor if you notice any of the following:

Frequent side effects:

Mouth

- sore mouth
- black hairy tongue
- sore throat

Skin

- pins and needles or numbness

Blood

- problems with blood clotting (unusual bleeding or bruising)
- infections or fever (may be caused by low white blood cells)
- anaemia (may cause lack of energy or tiredness)

Kidney

- kidney problems, which might cause blood in the urine or reduced amounts of urine

Liver

jaundice - yellowing of skin or whites of the eyes

Frequency unknown side effects:

- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (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.

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BETAPEN GRANULES.

5. How to store BETAPEN GRANULES

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Dry powder: Store at or below 25 ºC, Store in the original package.
- Reconstituted solution: Store up to 7 days to 2 °C - 8 °C in a refrigerator.

6. Contents of the pack and other information

What BETAPEN GRANULES contains

BETAPEN 125 mg GRANULES:

After reconstitution each 5 ml oral suspension contains phenoxymethylpenicillin potassium equivalent to 125 mg phenoxymethylpenicillin.

The other ingredients are:

- Col Red Rasberry H1277
- Trusil Cherry F 1496
- Saccharin Sodium
- Sucrose

BETAPEN 250 mg GRANULES:

After reconstitution each 5 ml oral suspension contains phenoxymethylpenicillin potassium equivalent to 250 mg phenoxymethylpenicillin.

The other ingredients are:

- Col Red Rasberry H1277
- Ess. Fl. Cherry DM 6040
- Saccharin Sodium
- Sucrose

What BETAPEN GRANULES looks like and contents of the pack

Granules

Granules (125 mg/5 ml and 250 mg/5 ml)

White to light pink granules.

Reconstituted Suspension (125 mg/5 ml and 250 mg/5 ml)

Clear red syrupy suspension with a cherry odour and almost sweet taste.

Contents of the pack:

BETAPEN 125 mg GRANULES:

Containers of granules for 60 ml and 100 ml suspension.

BETAPEN 250 mg GRANULES:

Containers of granules for 100 ml suspension.

Holder of Certificate of Registration

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Registration Numbers

BETAPEN 125 mg GRANULES:

B/20.1.2/90 (125 mg/5 ml) (South Africa)

S2 BOT 0901558 (Botswana) (125 mg/5 ml) 100 ml

NS2 90/20.1.2/00369 (125 mg/5 ml) (Namibia) 100 ml

BETAPEN 250 mg GRANULES:

B/20.1.2/203 (250 mg/5 ml) (South Africa)

NS2 90/20.1.2/00370 (250 mg /5 ml) Namibia)