

PACKAGE LEAFLET

Package leaflet: Information for the patient

Phenoxyethylpenicillin 500 mg film-coated tablets
(Phenoxyethylpenicillin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Phenoxyethylpenicillin film-coated tablets are and what it is used for
2. What you need to know before you take Phenoxyethylpenicillin film-coated tablets
3. How to take Phenoxyethylpenicillin film-coated tablets
4. Possible side effects
5. How to store Phenoxyethylpenicillin film-coated tablets
6. Contents of the pack and other information

1. What Phenoxyethylpenicillin film-coated tablets are and what it is used for

The name of your medicine is Phenoxyethylpenicillin film-coated tablets. Phenoxyethylpenicillin film-coated tablets belong to a family of medicines called antibiotics, in a group called 'penicillins'. Antibiotics are used to kill the bacteria or "germs" which cause infections.

Your doctor, or dentist, will have prescribed Phenoxyethylpenicillin film-coated tablets for treating an infection which is caused by bacteria which are sensitive to penicillin antibiotics.

2. What you need to know before you take Phenoxyethylpenicillin film-coated tablets

Do not take Phenoxyethylpenicillin film-coated tablets if:

- You are allergic to phenoxyethylpenicillin, or other 'penicillins' antibiotics or medicines.
- You are allergic to any of the other ingredients in Phenoxyethylpenicillin film-coated tablets (see section 6 Contents of the pack and other information).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Phenoxymethylpenicillin film-coated tablets if:

- You have bronchial asthma or suffer from a tendency to develop allergic conditions such as hayfever or eczema.
- You have any problems with your kidneys.
- You have suffered severe diarrhoea following previous treatment with antibiotics.
- You have a severe illness.
- 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.
- You are on a low potassium diet. Each Phenoxymethylpenicillin 500 mg film-coated tablets contains 28 mg of potassium. This potassium content needs to be taken into consideration by patients with kidney problems or patients on a controlled potassium diet.
- You have your urine tested for glucose using a non-enzymatic test, then Phenoxymethylpenicillin film-coated tablets may give a false positive result.
- You are on long term treatment with penicillin. Your doctor will have to monitor your progress when taking this medicine.
- You are pregnant or thinking of becoming pregnant
- You are breast-feeding.

Other Medicines and Phenoxymethylpenicillin film-coated tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are using the following:

- Uricosuric drugs (medicines used to treat gout and other conditions which require lowering of blood uric acid levels, e.g. probenecid and sulfinpyrazone).
- Anticoagulants (medicines that prevent the clotting of blood, e.g. warfarin, coumarin and phenindione).
- Any other antibiotics (such as tetracycline, erythromycin, chloramphenicol, sulphonamide).
- Methotrexate (a medicine used to treat cancer, psoriasis and rheumatoid arthritis).
- Guar gum (a medicine used to treat some types of diabetes).
- Neomycin (anti-fungal).
- The contraceptive pill, as phenoxymethylpenicillin potassium may reduce the effect of the pill, you should therefore take extra contraceptive precautions such as using a condom or a diaphragm with spermicide.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Phenoxymethylpenicillin film-coated tablets contain potassium

This medicine contains 28 mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Phenoxymethylpenicillin film-coated tablets

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

Each dose should be swallowed with a drink of water, at least 30 minutes before food. Try to space the doses as evenly as possible throughout the day.

The recommended dose is:

Adults:

The recommended dose for adults is 250 mg or 500 mg (i.e. one or two tablets) every 6 hours. This may vary depending on the type of infection you have.

If you have poor kidney function the dose may be lowered.

Use in children and adolescents:

For children aged 6 - 12 years of age the recommended dose is 250 mg (i.e. one tablet) every 6 hours.

For children aged 1 - 5 years of age the recommended dose is 125 mg (i.e. half a tablet) every 6 hours.

How long to take your medicine for:

Your doctor will tell you how long to take your medicine for based on the type of infection you have. 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 this medicine, your condition may re-occur or get worse.

If you take more Phenoxymethylpenicillin film-coated tablets than you should

Always take your medicine as recommended by your doctor. A large overdose may cause nausea (feeling sick), vomiting (being sick) and diarrhoea. Rarely seizures (fits) may occur. If you (or someone else) take too much medicine, or if you think a child has swallowed any of the tablets, tell your doctor immediately or go to your local hospital emergency department. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were swallowed.

If you forget to take Phenoxymethylpenicillin film-coated tablets

If you miss a dose, take another as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenoxymethylpenicillin film-coated tablets

Keep taking your medicine until the course is finished. Do not stop taking your tablets just because you feel better – if you stop too soon the infection may start up again.

When you have finished Phenoxymethylpenicillin film-coated tablets

If your symptoms persist, tell your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Phenoxymethylpenicillin film-coated tablets can cause side effects, although not everybody gets them.

Tell your doctor if you think your medicine is making you feel unwell or if you get any of the following side effects:

The following side effects are rare, however if you think you are having an allergic reaction stop taking your tablets and tell your doctor immediately or go to your local hospital emergency department as severe allergic reactions may require emergency treatment.

- An allergic reaction which may occur as:
 - a rash on your skin (which might be severe).
 - sudden wheeziness, breathing difficulties or tightness of the chest.
 - swelling of your eyes, lips, throat or tongue.
 - skin lumps and hives (“nettle rash”).
 - fever or joint pain.
 - dizziness.
 - allergic reactions may also cause effects to the blood and kidneys.

Other reported side effects:

- Diarrhoea (which may contain blood)

Should the diarrhoea be persistent and severe, stop taking your tablets and tell your doctor immediately or go to your local hospital emergency department.

- Fits or convulsions (usually following high doses or if you suffer from severe kidney damage).
- Numbness or tingling of the hands and feet.
- Vomiting, or nausea (a feeling of sickness).
- Inflammation of the tongue or mouth.
- Thrush or discharge from the vagina.
- Blood disorders. Symptoms of blood disorders include tiredness, sore throat, fever, unexplained bruising and bleeding, bruising easily and susceptibility to infection.
- Soft stools.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phenoxymethylpenicillin film-coated tablets

Keep this medicine out of the sight and reach of children.

Do not use Phenoxymethylpenicillin film-coated tablets after the expiry date which is stated on the carton or blister strip. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original packaging.

Do not use Phenoxymethylpenicillin film-coated tablets if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Phenoxymethylpenicillin contains

The active substance is phenoxymethylpenicillin. Each film coated tablet contains 500 mg of phenoxymethylpenicillin (as phenoxymethylpenicillin potassium).

The other ingredients are:
calcium hydrogen phosphate dihydrate,
maize starch,
microcrystalline cellulose,
magnesium stearate.

Film-coating ingredients are:
macrogol polyvinyl alcohol graft copolymer (E1209),
talc (E553b),
titanium dioxide (E171),
GMCC Type 1(E471),
polyvinyl alcohol-part. hydrolyzed (E1203).

What Phenoxymethylpenicillin film-coated tablets contain:

White to off white, circular, biconvex film coated tablet, with break line on one side and E41 on other side.

White opaque PVC-Al blister pack. Packs containing 10,14,20,28,30,50,56,60,84,98 & 100's tablets are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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