PHENOXYMETHYLPENICILLIN 250MG TABLETS
PL 19348/0063

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PHENOXYMETHYLPENICILLIN 250MG TABLETS
PL 19348/0063

LAY SUMMARY

On 2nd November 2010, the MHRA granted LPC Medical (UK) Limited a Marketing Authorisation (licence) for Phenoxymethylpenicillin 250mg Tablets (PL 19348/0063).

Phenoxymethylpenicillin 250mg Tablets contain phenoxymethylpenicillin potassium which belongs to a group of medicines called beta-lactamase resistant penicillins (antibiotic).

Phenoxymethylpenicillin potassium is an antibiotic that is used to treat infections caused by bacteria that are sensitive to penicillins. These infections include:

- Infections of the lungs (such as pneumonia and bronchitis).
- Ear and throat infections (such as otitis media and pharyngitis).
- Other infections (such as infections of the skin and soft tissue, scarlet fever and erysipelas).

Phenoxymethylpenicillin is also used to prevent infections such as:

- Prevention of recurrent attacks of rheumatic fever.
- Prevention of lung infections in patients with no spleen or sickle cell disease.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Phenoxymethylpenicillin 250mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.

PHENOXYMETHYLPENICILLIN 250MG TABLETS
PL 19348/0063

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Phenoxymethylpenicillin 250mg Tablets (PL 19348/0063) to LPC Medical (UK) Limited on 2nd November 2010. This prescription only medicine is indicated for the treatment of bacterial infections where a sensitive organism is suspected or proven. Phenoxymethylpenicillin should not be used for serious infections because absorption can be unpredictable and plasma concentrations variable.

The product is indicated for infections in the:

- Lower respiratory tract: pneumonia, bronchitis
- Upper respiratory tract: bacterial pharyngitis, otitis media
- Others: skin and soft tissues infections, scarlatina, erysipelas, prophylaxis of rheumatic fever and pneumococcal infection prophylaxis in asplenia or patients with sickle cell disease.

This application for Phenoxymethylpenicillin 250mg Tablets is submitted according to Article 10c of Directive 2001/83/EC, cross-referring to Phenoxymethylpenicllin potassium Tablets BP 250mg, which was originally approved and licensed to Rivopharm SA (PL 01587/0001) on 25th July 1988. This went through a change of ownership on 9th June 2003 to Karib Kemi-Pharm Limited (PL 18224/0049).

No new data were submitted nor were they necessary for this “simple” application, as the data are identical to that of the previously granted cross-reference product.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 19348/0063
PROPRIETARY NAME: Phenoxymethylpenicillin 250mg Tablets
ACTIVE(S): Phenoxymethylpenicillin potassium
COMPANY NAME: LPC Medical (UK) Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

This is a "simple" application for Phenoxymethylpenicillin 250mg Tablets (PL 19348/0063) submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is LPC Medical (UK) Limited, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, United Kingdom.

This application cross-refers to Phenoxymethylpenicllin potassium Tablets BP 250mg, which was originally approved and licensed to Rivopharm SA (PL 01587/0001) on 25th July 1988. This went through a change of ownership on 9th June 2003 to Karib Kemi-Pharm Limited (PL 18224/0049).

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)

The proposed name of the product is Phenoxymethylpenicillin 250mg Tablets. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains phenoxymethylpenicllin potassium. The finished product is packaged in:

- Polypropylene containers with pilfer proof polyethylene closures.
- Blister packs made of polyvinyl chloride and aluminium.

Pack sizes are:
Polypropylene containers: 28 or 100 or 500 or 1000 tablets.
Blister packs: 28, 100, 112, 250, 252, 500, 504, 1000 and 1008 tablets.

The proposed shelf-life is 36 months with storage conditions:
Polypropylene containers: Do not store above 25°C. Keep the container tightly closed.
Blister packs: Do not store above 25°C. Store in the original container.
This is consistent with the details registered for the cross-reference product.

2.3 Legal status

Prescription only medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company

LPC Medical (UK) Limited, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size for each product is stated.

2.8 Finished product/shelf-life specification
The finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
None of the excipients used contain material of animal or human origin, which is supported by a statement from the Quality Expert. The supplier of magnesium stearate has confirmed that it is of vegetable origin. This information is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. The Marketing Authorisation Holder has stated that it is not intending to market the product and, thus, no PIL user testing has been submitted. The Marketing Authorisation Holder has committed to submit PIL user testing for review to the regulatory authority before marketing the product.

The product shall not be marketed in the UK until approval of the leaflets has been obtained in accordance with Article 59 of Council Directive 2001/83/EC.

Labelling

The artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has included the name of the product in Braille on the packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously approved for the cross-reference product and, as such, has been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to the previously granted application Phenoxymethylpenicllin potassium Tablets BP 250mg, which was originally approved and licensed to Rivopharm SA (PL 01587/0001) on 25th July 1988. This went through a change of ownership on 9th June 2003 to Karib Kemi-Pharm Limited (PL 18224/0049).

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with phenoxymethylpenicillin potassium is considered to have demonstrated the therapeutic value of the compounds. The risk:benefit is, therefore, considered to be positive.

PHENOXYMETHYLPENICILLIN 250MG TABLETS
PL 19348/0063

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the Marketing Authorisation Application on 27th April 2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 4th July 2006.
3	Following assessment of the application further information was requested regarding the quality section of the dossier on 28th November 2006.
4	The applicant responded to the MHRA's requests, providing further information on 2nd November 2007 for the quality section.
5	The application was determined on 1st November 2010.

PHENOXYMETHYLPENICILLIN 250MG TABLETS
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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Phenoxymethylpenicillin 250 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:
Phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 250 mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Shiny white, flat tablets with k logo on one side and break line on the other.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
Phenoxymethylpenicillin potassium is an orally active penicillin indicated for treatment of bacterial infections where a sensitive organism is suspected or proven. Phenoxymethylpenicillin should not be used for serious infections because absorption can be unpredictable and plasma concentrations variable.

Lower respiratory tract: pneumonia, bronchitis
Upper respiratory tract: bacterial pharyngitis, otitis media
Others: skin and soft tissues infections, scarlatina, erysipelas, prophylaxis of rheumatic fever and pneumococcal infection prophylaxis in asplenia or patients with sickle cell disease.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Posology
The dose will depend upon the severity, type and site of infection.
In general the treatment must be continued 2-3 days after improvement of the symptoms.

For children
- 1-5 years of age : 125 mg every 6 hours
- 6-12 years of age : 250 mg every 6 hours or as prescribed

For adults (including elderly)
Standard dosage : 250-500 mg every 6 hours or as directed by a medical practitioner.

Prevention of recurrence of rheumatic fever: 250mg twice daily

Prevention of pneumococcal infection in asplenia or sickle cell disease:
Adult : 500mg every 12 hours
Child under 5 years : 125mg every 12 hours
Child 6-12 years : 250mg every 12 hours

Special dosage : The elimination of phenoxymethylpenicillin potassium is reduced in case of renal insufficiency.
The dose interval should be adjusted to every 8 hours to 12 hours according to the severity of renal impairment.
The recommended dose is to be taken about half an hour before meals.

Method of administration
Oral.

4.3 CONTRAINDICATIONS
Phenoxymethylpenicillin potassium should not be given to patients with a history of penicillin hypersensitivity.
Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics e.g. cephalosporins. Severe acute infections should not be treated with phenoxymethylpenicillm.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

All degrees of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin. These reactions are more likely to occur in individuals with a history of sensitivity to penicillins, cephalosporins and other allergens.

Enquiry should be made for such a history before therapy with a penicillin begins. If an allergic reaction occurs, the drug should be discontinued and the patient treated with the usual agents (eg Adrenaline and other pressor amines, antihistamines and corticosteroids).

Oral therapy should not be relied upon in patients with severe illness, or with nausea, vomiting, gastric dilation, cardiospasm or intestinal hypermotility.

Occasionally, patients do not absorb therapeutic amounts of orally administered penicillin. Administer with caution in the presence of markedly impaired renal function, as the safe dosage may be lower than usually recommended.

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.

Prolonged use of antibiotics may promote the overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, appropriate measures should be taken.

Caution should be used when treating patients with a history of antibiotic-associated colitis.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or gluclose-galactose malabsorpation should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Probenecid delays the elimination of penicillin through the kidneys and thus prolongs its action.
Phenoxymethylpenicillin reduces the excretion of the cytotoxic drug, methotrexate.
Avoid concomitant administration with bacteriostatic antibiotics such as tetracycline, erythromycin, chloramphenicol 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 contraceptive precautions while taking phenoxymethylpenicillin.
The simultaneous administration of guar gum diminishes the absorption of penicillins.

4.6 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 studies. However, as with other drugs, caution should be exercised when prescribing to pregnant patients.

Lactation

Breast feeding 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

None known.

4.8 UNDESIRABLE EFFECTS

Hypersensitivity

Although reactions have been reported much less frequently after oral than after parenteral therapy, it should be remembered that all degrees of hypersensitivity, including fatal anaphylaxis, have been observed with oral penicillin.

The hypersensitivity reactions noted include urticaria, fever, joint pains, rashes, angioedema, anaphylaxis, serum sickness like reactions, haemolytic anaemia and interstitial nephritis.

Gastro-intestinal tract

Phenoxymethylpenicillin potassium is generally well tolerated. Occasionally soft stools occur and they do not require the interruption of the treatment.

Digestive troubles with nausea and/or vomiting rarely appear. Severe and persistent diarrhoeas can be the symptoms of pseudomembranous colitis. This requires immediate attention and treatment with an appropriate antibiotherapy (i.e. vancomycin).

Blood

Possible effects on the blood composition: neutropenia or leucopenia, thrombocytopenia, haemolytic anaemia and coagulation disorders.

Central nervous system

Central nervous system toxicity, including convulsions, has been reported, especially following high doses or in severe renal impairment. Paraesthesia has been reported with prolonged use.

4.9 OVERDOSE

Cases of intended or accidental overdosage should be brought under medical supervision for symptomatic treatment. It is advisable to monitor blood levels in patients with renal malfunction.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Phenoxymethylpenicillin potassium is a beta lactam antibiotic with bactericidal action against Gram-positive bacteria and Gram-negative cocci. Its antimicrobial action is similar to that of benzyl penicillin. Phenoxymethylpenicillin potassium is usually active against the following organisms:

Gram-positive aerobes and anaerobes including
Bacillus anthracis
Clostridium perfringens
Clostridium tetani
Corynebacterium diphtheriae
Erysipelothrix rhusiopathiae
Listeria monocytogenes
Peptostreptococcus spp.
Streptococcus agalactiae (Group *B)*
Streptococcus pneumoniae
Streptococcus pyogenes (Group *A)*
Gram-negative including
Neisseria meningitidis
Neisseria gonorrhoeae

Phenoxymethylpenicillin potassium is inactivated by penicillinase and other beta lactamases. Phenoxymethylpenicillin binds to penicillin-binding proteins located on the inner membrane of the bacterial cell wall. Phenoxymethylpenicillin binds to and inactivates these proteins resulting in weakening of the bacterial cell wall and lysis.

5.2 PHARMACOKINETIC PROPERTIES

Phenoxymethylpenicillin is stable under acidic conditions so it can be administered by oral route. Phenoxymethylpenicillin is rapidly, but incompletely absorbed after oral administration and the absorption level is around 60%. The simultaneous administration of food slightly decreases the peak plasma concentration of phenoxymethylpenicillin, but does not appear to affect the extent of absorption. Peak plasma concentrations are reached in about 45 minutes. The peak plasma concentration increases approximately in proportion with increased doses.

Phenoxymethylpenicillin is partially metabolised to inactive penicilloic acid by hydrolysis of the lactam ring. This metabolism occurs in the liver.
Phenoxymethylpenicillin passes into the tissues (volume of distribution about 0.2 l.kg-1 of body weight.
The plasma protein binding is about 80% .
About 40% of the dose is eliminated in the urine either as under unchanged or as penicilloic acid in the first 10 hours after oral administration.
The plasma half-life of phenoxymethylpenicillin is about 45 minutes. It is however extended in case of renal insufficiency.

5.3 PRECLINICAL SAFETY DATA

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SPC

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The excipients in the tablet are: lactose, maize starch, magnesium stearate and pregelatinised starch.

6.2 INCOMPATIBILITIES

None known.

6.3 SHELF LIFE

The shelf life of the product is 36 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

For containers: Do not store above 25^{o}C. Keep the container tightly closed

For Blister packs: Do not store above 25^{o}C. Store in the original container.

6.5 NATURE AND CONTENTS OF CONTAINER

Polypropylene container with pilfer proof polyethylene closure containing 28 or 100 or 500 or 1000 tablets.

PVC/Aluminium blister packs of 28, 100, 112, 250, 252, 500, 504, 1000 and 1008 tablets.

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

The tablets should be swallowed with water.

7 MARKETING AUTHORISATION HOLDER

LPC Medical (UK) Ltd
30 Chaul End Lane
Luton, Bedfordshire
LU4 8EZ
United Kingdom
Tel: +44 (0)1582 560393
Fax: +44 (0)1582 569009
e-mail: info@lpcpharma.com

8 MARKETING AUTHORISATION NUMBER(S)

PL 19348/0063

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/11/2010

10 DATE OF REVISION OF THE TEXT

02/11/2010

Patient information leaflet

PHENOXYMETHYLPENICILLIN 250mg TABLETS BP

Read all of this leaflet carefully before you start taking this medicine.

About your medicine

What is in my medicine?
The name of your medicine is Phenoxymethylpenicillin 250mg Tablets.

Each tablet contains 250mg of Phenoxymethylpenicillin potassium as the active ingredient.

In addition, the tablet contains a number of inactive ingredients.

The inactive ingredients are: lactose, talc, magnesium stearate and starch.

Phenoxymethylpenicillin Potassium tablets are shiny white, flat tablets with bevel edge and embossed with Ⓚ on one side and breakline on the other and come in bottles of 100, 500 and 1000 tablets and blister packs of 28 and 504 tablets.

What type of medicine is Phenoxymethylpenicillin Potassium?
Phenoxymethylpenicillin Potassium is an antibiotic.

What is my medicine for?
Phenoxymethylpenicillin potassium is an antibiotic that is used to treat infections caused by bacteria that are sensitive to penicillins. These infections include:

- Infections of the lungs (such as pneumonia and bronchitis).
- Ear and throat infections (such as otitis media and pharyngitis).
- Other infections (such as infections of the skin and soft tissue, scarlet fever and erysipelas).

Phenoxymethylpenicillin is also used to prevent infections such as:
- Prevention of recurrent attacks of rheumatic fever.
- Prevention of lung infections in patients with no spleen or sickle cell disease.

Before taking your medication
Do not take this medicine if you:
Are allergic to any penicillin or cephalosporin antibiotics, or any of the other ingredients shown above.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tell your doctor if you:
- Have a history of allergies.
- Have kidney disease.
- Have suffered severe diarrhoea following previous treatment with antibiotics.
- Have a severe illness.
- 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 been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Pregnancy and breastfeeding:
Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding.

Interactions with other medicines
Let your doctor know about any other medicines you are currently taking including: other antibiotics (such as tetracyclines, erythromycin, chloramphenicol, sulphonamides), probenecid (used for the treatment of gout), methotrexate (used in the treatment of severe rheumatoid arthritis, severe psoriasis and cancer) and guar gum (used in the treatment of diabetes). Phenoxymethylpenicillin may interfere with the way the contraceptive pill works. If you are taking the Pill you should use additional precautions (such as a condom or diaphragm) for the cycle during which you took the antibiotic.

Taking your medicine
The dosage prescribed will depend upon the type and severity of the infection. Always follow your doctor's instructions and ask your pharmacist or doctor if you are unsure on how to take your medicine.
In general the treatment must be continued 2-3 days after improvement of the symptoms. It is important that you complete the entire course of medicine your doctor has prescribed for you. Do not stop taking the tablets if you feel better, as your infection may come back or get worse.

Treatment of Infection
Adults: 250-500mg every 6 hours or as directed by your doctor.
Child 1-5 years of age: 125mg every 6 hours.
Child 6-12 years of age: 250mg every 6 hours or as directed by your doctor.

Prevention of Infection
Rheumatic fever: 250mg twice daily.

Lung infection in patients with no spleen or sickle cell disease:
Adults: 500mg every 12 hours.
Child aged 6-12 years: 250mg every 12 hours.
Child under 5 years: 125mg every 12 hours.

If you have kidney damage your doctor may give you a different dose.

You should swallow this medicine with water about half an hour before meals.

If you forget to take your medicine take it as soon as you remember. Do NOT take two doses together.

If you or a child ever takes too much medicine contact your doctor or local casualty department immediately. Take any remaining tablets and this leaflet to show to your doctor.

Undesirable effects
Phenoxymethylpenicillin potassium is generally well tolerated. Occasionally soft stools occur but this does not require treatment. However, if you develop severe diarrhoea, which may contain blood, you should contact your doctor immediately.

This package leaflet was last revised in October 2007.

Feeling or being sick is a rare reaction.

Allergic reactions can occur, which may rarely be severe. Stop taking the tablets and contact a doctor immediately if you notice skin rashes, which may be itchy raised or red, fever, joint pains, swelling of the face, lips, throat or tongue, breathing difficulties or dizziness. Allergic reactions may also include effects on the blood and kidney.

Effects on the nervous system occur rarely and are more likely if you have an injection of an antibiotic or have severe kidney damage. If you experience numbness or tingling of the hands or feet, or fits, you should see your doctor.

Phenoxymethylpenicillin may alter the number and type of blood cells. If you notice you have more nose bleeds, bruise easily or have frequent infections talk to your doctor who may want to test your blood.

If you should suffer from any undesirable effect not listed above, you should report it to your doctor or pharmacist.

Who makes my medicine?
The Product Licence Holder for Phenoxymethylpenicillin Potassium tablets is LPC Medical (UK) Limited, 30 Chaul End Lane, Luton, Bedfordshire LU4 8EZ, U.K.

The manufacturer and distributor for Phenoxymethylpenicillin Potassium tablets is Karib Kemi Pharm Limited, Karib House, 63-65 Imperial Way, Croydon, Surrey CR0 4RR, U.K.

Storage
Do not store above 25°C. Store in original package. Keep the container tightly closed.
Keep out of the reach and sight of children.
If your doctor decides to stop the treatment, return any tablets left over the pharmacist. Only keep them if your doctor tells you to.

Do not use after the expiry date printed on the package.

Important reminder: Do not give your medicine to anyone else, even if they suffer from the same condition as you. This medicine could be harmful to them or interfere with other treatments. Your medicine has been prescribed by your doctor specifically for you.

PL 19348/0063 POM

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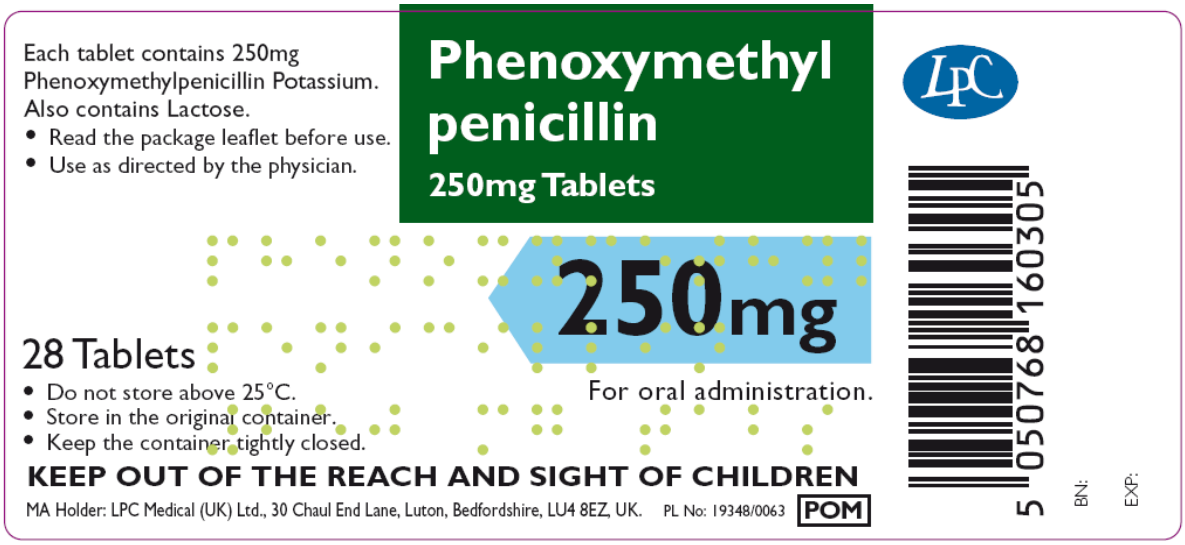
Phenoxymethylpenicillin 250mg Tablets
Each tablet contains 250mg Phenoxymethylpenicillin Potassium.
Also contains Lactose.
• Read the package leaflet before use.
• Use as directed by the physician.
• Do not store above 25°C.
• Store in the original package.
Please affix dispensing label here
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
Phenoxymethylpenicillin
250mg Tablets
28 Tablets
250mg
BN:
EXP:
Phenoxymethylpenicillin
250mg Tablets
250mg
For oral administration.
PL 19348/0063
POM
MA Holder: LPC Medical (UK) Ltd.,
30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, UK.
5 050768 160305


Each tablet contains 250mg Phenoxymethylpenicillin Potassium.
Also contains Lactose.
• Read the package leaflet before use.
• Use as directed by the physician.
Phenoxymethyl penicillin
250mg Tablets
250mg
For oral administration.
28 Tablets
• Do not store above 25°C.
• Store in the original container.
• Keep the container tightly closed.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
MA Holder: LPC Medical (UK) Ltd., 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, UK. PL No: 19348/0063 POM
5 050768 160305
BN:
EXP: