Medicines & Healthcare products
Regulatory Agency

# Public Assessment Report

# National Procedure

# Phenoxymethylpenicillin 250 mg Tablets

# phenoxymethylpenicillin potassium

# PL 43461/0115

# Flamingo Pharma UK Ltd.

# LAY SUMMARY

## Phenoxymethylpenicillin 250 mg Tablets
## phenoxymethylpenicillin potassium

This is a summary of the Public Assessment Report (PAR) for Phenoxymethylpenicillin 250 mg Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Phenoxymethylpenicillin in this lay summary for ease of reading.

For practical information about using Phenoxymethylpenicillin, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

**What is Phenoxymethylpenicillin and what is it used for?**
This application is the same as Phenoxymethylpenicillin 250mg tablets (PL 43461/0073) which is already authorised.

The Company responsible for Phenoxymethylpenicillin 250mg tablets has agreed that its scientific data can be used as the basis for the grant of an identical licence for Phenoxymethylpenicillin.

Phenoxymethylpenicillin 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, respiratory tract, scarlet fever and erysipelas)

Phenoxymethylpenicillin is also used to prevent infections such as:
• Prevention of recurrent attacks of rheumatic fever or chorea (infection of the nervous system)
• Prevention of lung infections in patients with no spleen or sickle cell disease
• Prevention of pneumococcal infection (e.g. in asplenia)

**How does Phenoxymethylpenicillin work?**
Phenoxymethylpenicillin, is an antibiotic, which belongs to a group of medicines called penicillins, which are used to kill bacteria that cause infections in the body.
Each tablet contains 250mg of Phenoxymethylpenicillin potassium as the active ingredient.

**How is Phenoxymethylpenicillin used?**
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth).

The dosage prescribed will depend upon the type and severity of the infection.
In general the treatment must be continued 2-3 days after improvement of the symptoms. It is important that the patient completes the entire course of medicine their doctor has prescribed for them.

Treatment of Infection
**Adults:** 250-500mg every 6 hours or as directed by a 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 a 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 a patient has kidney damage their doctor may give them a different dose. Dosage might be changed by the patient's doctor if the patient has liver problems along with kidney problem.

When to take the medicine
Phenoxymethylpenicillin contains lactose. The tablet is usually prescribed to be taken four times a day. It is best to take it as evenly spaced as possible. Patients should take this medicine when their stomach is empty. Patients should swallow this medicine about half an hour before meals.

For further information on how Phenoxymethylpenicillin is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

**What benefits of Phenoxymethylpenicillin have been shown in studies?**
Phenoxymethylpenicillin is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Phenoxymethylpenicillin, however, reference is made to the studies for Phenoxymethylpenicillin 250mg tablets.

**What are the possible side effects of Phenoxymethylpenicillin?**
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Phenoxymethylpenicillin is considered to be identical to the previously authorised product with the same benefits and risks.

**Why was Phenoxymethylpenicillin approved?**
The MHRA decided that the benefits of Phenoxymethylpenicillin are greater than the risks and recommended that this medicine is approved for use.

**What measures are being taken to ensure the safe and effective use of Phenoxymethylpenicillin?**
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Phenoxymethylpenicillin The RMP details the important risks of Phenoxymethylpenicillin, how these risks can be minimised, any uncertainties about Phenoxymethylpenicillin (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Phenoxymethylpenicillin:

| **Summary of safety concerns** | |
|---|---|
| Important identified risks | • Hypersensitivity to penicillins.<br>• Diarrhoea/pseudomembranous colitis caused by Clostridium difficile |
| Important potential risks | • Drugs interactions (methotrexate).<br>• Use in patients with phenylketonuria.<br>• Use in patients with fructose intolerance. |
| Missing information | • None |

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Phenoxymethylpenicillin are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

**Other information about Phenoxymethylpenicillin**
A marketing authorisation was granted in the UK on 28 February 2024.

The full PAR for Phenoxymethylpenicillin follows this summary.

This summary was last updated in April 2024.

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## I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Phenoxymethylpenicillin 250 mg Tablets (PL 43461/0115) could be approved.

The product is indicated for treatment or prophylaxis of mild to moderately severe infections caused by penicillin sensitive organisms, i.e. those micro-organisms whose susceptibility to penicillin is within the range of serum levels attained with the dosage form.

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, Vincent's gingivitis, prophylaxis of rheumatic fever/or chorea and pneumococcal infection prophylaxis in asplenia or patients with sickle cell disease.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The active substance, 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*

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product Phenoxymethylpenicillin 250mg tablets (PL 43461/0073).

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation was granted in the UK on 28 February 2024.

## II. EXPERT REPORT

The applicant cross-refers to the data for Phenoxymethylpenicillin 250mg tablets (Flamingo Pharma, UK), to which this application is claimed to be identical. This is acceptable.

## III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Phenoxymethylpenicillin 250mg tablets, dated 28 November 2023.

## PATIENT INFORMATION LEAFLET

A leaflet text and mock-up has been provided which has been aligned with that for Phenoxymethylpenicillin 250mg tablets, dated for 12/2023.

## LABEL

Label text and mock-ups have been provided.

## IV. QUALITY ASPECTS

### IV.1 Drug Substance

**Drug substance specification**

The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

### IV.2. Drug Product

**Name**

The product has been named in line with current requirements.

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

Phenoxymethylpenicillin 250 mg Tablets are available in Aluminium-PVC/PVDC blisters in pack sizes of 28, 100, 112, 250, 252, 500, 504, 1000 and 1008 tablets.

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 36 months with <no special storage conditions/with the recommended storage conditions do not store above 25°C and store in the original package.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

**Legal status**

Prescription only medicine (POM)

**Manufacturers**
The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

**Qualitative and quantitative compositions**
The composition of the proposed product is consistent with the details registered for the cross-reference product.

**Manufacturing process & control of critical steps**
The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

**Finished product release/shelf life specifications**
The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

**TSE Compliance**
With the exception of lactose, no excipients of animal or human origin are used in the final products.

The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

This product does not contain or consist of genetically modified organisms (GMO).

## V. NON-CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new non-clinical data have been supplied and none are required.

## VI. CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new clinical data have been supplied and none are required.

## VII. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

## VIII. USER CONSULTATION
A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

## IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
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. The

benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

| **Application type** | **Scope** | **Product information affected** | **Date of grant** | **Outcome** | **Assessment report attached Y/N** |
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