Public Assessment Report

Decentralised Procedure

Cefpodoxime 100 mg and 200 mg film-coated tablets (Cefpodoxime proxetil)

Procedure No: UK/H/1137/001-2/DC

UK Licence No: PL 16363/0336-337

Milpharm Limited
LAY SUMMARY

Cefpodoxime 100 mg and 200 mg film-coated tablets
(cefpodoxime proxetil, film-coated tablet, 100 mg and 200 mg)

This is a summary of the Public Assessment Report (PAR) for Cefpodoxime 100 mg and 200 mg film-coated tablets (PL 20532/0111-112; UK/H/1137/001-2/DC). It explains how Cefpodoxime 100 mg and 200 mg film-coated tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Cefpodoxime 100 mg and 200 mg film-coated tablets.

The products will be collectively referred to as Cefpodoxime throughout the remainder of this public assessment report (PAR).

For practical information about using Cefpodoxime, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cefpodoxime and what is it used for?
Cefpodoxime 100 mg film-coated tablets are a ‘generic medicine’. This means that Cefpodoxime 100 mg film-coated tablets is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Orelox tablets 100 mg film coated tablets (Laboratoires Aventis, France).

Cefpodoxime 200 mg film-coated tablets are a ‘hybrid generic medicine’. This means that it is similar to a ‘reference medicine’ containing the same active substance but is available as a different strength.

The company has provided additional own data to demonstrate the safety and efficacy of Cefpodoxime 200 mg film-coated tablets regarding this difference from the reference medicine.

The reference medicine for Cefpodoxime 200 mg film-coated tablets is Orelox tablets 100 mg film coated tablets (Laboratoires Aventis, France).

Cefpodoxime is used for the treatment of the following infections:
- tonsilitis
- sinusitis
- acute chest infection in patients with chronic bronchitis
- pneumonia

How does Cefpodoxime work?
The active ingredient, cefpodoxime proxetil is an antibiotic used to kill bacteria, which cause infection in your body. It belongs to a group of antibiotics called cephalosporins.

How is Cefpodoxime used?
The pharmaceutical form of this medicine is a film-coated tablet, and the route of administration is oral (by mouth).

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

The recommended dose of this medicine is as follows:
Adults and Elderly with no kidney problems:
Infections of the sinuses: 200 mg twice daily.
Tonsilitis: 100 mg twice daily.
Chest infections and Pneumonia: 200 mg twice daily

Adults with kidney problems:
Depending on how serious the kidney problems are, the usual dose of cefpodoxime for the
type of infection the patient has may need to be given only once a day instead of twice a day
or even once every two days. The patient’s doctor will decide how much they need to take.
If the patient is on haemodialysis they will usually be given a dose after each dialysis session.
The patient’s doctor will tell them how much to take each time.

How to take:
It is important that the patient takes their medicine at the right times of day. They should
always take the tablets with food because food helps the tablets to absorb.

Please read section 3 of the package leaflet for detailed dosing recommendations, the route of
administration, and the duration of treatment.

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

This medicine can only be obtained with a prescription.

What benefits of Cefpodoxime have been shown in studies?
Because Cefpodoxime 100 mg film-coated tablets is a generic medicine and Cefpodoxime
200 mg film-coated tablets is a hybrid generic medicine, studies in patients have been limited
to tests to determine that they are bioequivalent to the reference medicine. Two medicines are
bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Cefpodoxime?
Like all medicines, Cefpodoxime can cause side effects, although not everybody gets them.
The patient should tell their doctor if they have any of the following side effects while they
are taking this medicine.

Common: (may affect up to 1 in 10 people):
- Stomach problems: Bloating nausea, vomiting, stomach pain, flatulence (wind) and
diarrhoea.
If the patient has severe diarrhoea or if the patient sees blood in their diarrhoea they should
stop taking this medicine and talk to their doctor immediately.
- Eating problems: loss of appetite.

For the full list of restrictions, see the package leaflet.

For the full list of all side effects reported with Cefpodoxime, see section 4 of the package
leaflet available on the MHRA website.

Why was Cefpodoxime approved?
It was concluded that, in accordance with EU requirements, Cefpodoxime has been shown to
have comparable quality and to be bioequivalent to the reference product. Therefore, the
MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that they can be approved for use.

**What measures are being taken to ensure the safe and effective use of Cefpodoxime?**

Safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for Cefpodoxime including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

**Other information about Cefpodoxime**

Austria, Germany, Spain, France and Italy and the UK agreed to grant Marketing Authorisations for Cefpodoxime on 18 August 2011. Marketing Authorisations were granted in the UK on 16 September 2011.

The Marketing Authorisations underwent a change of ownership from the company Aurobindo Pharma Limited (PL 20532/0111-112) to the company Milpharm Limited (PL 16363/0336-337) on 15 March 2012.

The full PAR for Cefpodoxime follows this summary.

For more information about treatment with Cefpodoxime, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2016.
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I INTRODUCTION

Please note that the below scientific discussion consists of the original assessment of this product licence, plus a summary of key post approval changes at the end of this introduction section to improve the accuracy of this Public Assessment Report.

Based on the review of the data on quality, safety and efficacy, the member states considered that these applications for Cefpodoxime 100 mg and 200 mg film-coated tablets (PL 20532/0111-2; UK/H/1137/001-2/DC) could be approved. These products are prescription-only medicines (POM) indicated for treatment of the following infections, when caused by susceptible pathogens in adults:

- Upper respiratory tract infections
  - acute bacterial sinusitis
  - tonsillitis (for 100 mg tablets only)

- Lower respiratory tract infections
  - acute exacerbation of chronic bronchitis
  - bacterial pneumonia - cefpodoxime might not be a suitable option depending on the pathogen involved.

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

These applications were submitted via the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and:

For Cefpodoxime 100 mg film-coated tablets (PL 20532/0111; UK/H/1137/001/DC):
Austria, Spain and Italy as Concerned Member States (CMS).

For Cefpodoxime 200 mg film-coated tablets (PL 20532/0112; UK/H/1137/001/DC):
Austria, Germany, Spain and Italy as Concerned Member States (CMS).

These applications were submitted under Article 10.1 (for the 100 mg film-coated tablets) and 10.3 (for the 200 mg film-coated tablets) of Directive 2001/83/EC. The reference products for these applications are Orelox tablets 100 mg film-coated tablets (Laboratoires Aventis, France) and Otreon 200 mg film-coated tablets (Daiichi Sankyo Austria GmbH, Austria), which were first authorized on 02 August 1990 and 13 October 1993, respectively.

Cefpodoxime proxetil is a broad-spectrum, semi-synthetic, beta-lactam antibiotic, a third-generation oral cephalosporin. It is the prodrug of cefpodoxime. Following oral administration, cefpodoxime proxetil is taken up by the gastrointestinal wall, where it is rapidly hydrolysed to cefpodoxime, a bactericidal antibiotic, which is then absorbed systemically. The mechanism of action of cefpodoxime proxetil is based on inhibition of the bacterial cell wall. It is active against a wide range of Gram-negative and Gram-positive organisms.

No new non-clinical data have been submitted, which is acceptable given that these are generic and hybrid applications based on originator products that have been in clinical use for over 10 years.

Two single-dose, bioequivalence studies were submitted to support these applications, comparing the test products Cefpodoxime 100 mg and 200 mg film-coated tablets (Aurobindo Pharma Limited, UK) with the reference products Orelox 100 mg film-coated tablets (Laboratoires Aventis, France).
tablets (Laboratorie Aventis, France) and Orelox 200 mg film-coated tablets (Aventis Pharma Deutschland, Germany), respectively. The bioequivalence studies were carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence studies, no new clinical data have been submitted, which is acceptable given that these are generic and hybrid applications based on originator products that have been in clinical use for over 10 years.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of these products. For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The RMS and CMS considered that the application could be approved at the end of procedure (Day 210) on 18 August 2011. After a subsequent national phase, licences were granted in the UK on 16 September 2011.

The Marketing Authorisations underwent a change of ownership from the company Aurobindo Pharma Limited (PL 20532/0111-112) to the company Milpharm Limited (PL 16363/0336-337) on 15 March 2012.

Summary of key post-approval changes:
The following post-approval variations have been granted for these licences:

1. To extend the shelf life of the finished product from 2 years to 3 years granted on 03 July 2015 (PL 16363/0336-0010 & PL 16363/0337-0010).
II QUALITY ASPECTS

II.1 Introduction
Each film-coated tablet contains 130.45 mg cefpodoxime proxetil equivalent to 100 mg cefpodoxime or 260.90 mg cefpodoxime proxetil equivalent to 200 mg cefpodoxime. Other ingredients consist of the pharmaceutical excipients, namely carmellose calcium, lactose monohydrate, hydroxy propyl cellulose, sodium lauryl sulphate, crospovidone (Type B), maize starch, magnesium stearate, hypromellose, titanium dioxide (E171), Sunset yellow FCF aluminium lake (E110), propylene glycol (1520), iron oxide yellow (E172 – 100mg tablets only) and Allura red AC aluminium lake (E129 - 200 mg tablets only). Appropriate justifications for the inclusion of each excipient have been provided.

The tablets are packaged in triple-laminated film (polyamide/aluminium/polyvinylchloride) blister packs in a carton, in pack sizes of 6, 7, 10, 12, 14, 15, 20, 30 and 50 film-coated tablets.

It has been stated that not all pack sizes may be marketed, however, the marketing authorisation holder has committed to submitting the mock-ups for any pack size to the relevant regulatory authorities for approval before marketing.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with foodstuff.

II.2 Drug substance
rINN: Cefpodoxime proxetil

Structure:

```
H3C
O
O

H2N
\H

OCH3
```

Molecular formula: C_{21}H_{27}N_{5} O_{9}S_{2}
Molecular Mass: 557.61
Appearance: A white to light-brownish white powder. Freely soluble in dehydrated alcohol, soluble in acetonitrile and in methanol, slightly soluble in ether and practically insoluble in water.

Cefpodoxime proxetil was not the subject of European Pharmacopoeia monograph at the time of assessment.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.
An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specification.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised. Satisfactory Certificates of Analysis have been provided for all reference standards. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with foodstuff.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3. Medicinal Product Pharmaceutical Development

The objective of the development programme was to produce safe, efficacious products that could be considered comparable in performance to Orelox tablets 100 mg film-coated tablets (Laboratoires Aventis, France) and Orelox 200 mg Film-coated tablets (Aventis Pharma Deutschland, Germany)

Suitable pharmaceutical development data have been provided for these applications.

Comparative dissolution and impurity profiles have been provided for these products and their respective reference products.

With the exception of iron oxide yellow (E172), Sunset yellow FCF aluminium lake (E110) and Allura red AC aluminium lake (E129), all excipients comply with their respective European Pharmacopoeia monographs. Sunset yellow FCF Aluminium Lake (E110) and Allura red AC aluminium lake (E129) are controlled to suitable in-house monographs. Iron oxide (E172) is controlled to National Formulary specifications. Iron oxide yellow (E172), Sunset yellow FCF aluminium lake (E110) and Allura red AC aluminium lake (E129) are also in compliance with current European Directives concerning use of colouring agents in foodstuff. Satisfactory Certificates of Analysis have been provided for all excipients, showing compliance with the proposed specifications.

With the exception of lactose monohydrate, none of the excipients used contain materials of animal or human origin. The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

No genetically modified organisms (GMO) have been used in the preparation of these excipients.

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. Process validation studies were conducted on two pilot-scale batches and the results were satisfactory. The validation data demonstrated consistency of the manufacturing process. A commitment has been made by the Marketing Authorisation Holder that full process validation will be conducted on the first three commercial-scale batches, in accordance with the process validation protocol.
**Finished Product Specification**
The finished product specifications proposed are acceptable. Test methods have been described and have been adequately validated. Batch data have been provided and comply with the release specifications. Certificates of Analysis have been provided for all reference standards used.

**Stability of the Product**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years, with the storage conditions ‘Store below 25°C.’

**Bioequivalence/Bioavailability**
Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study.

**Summaries of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels**
The SmPCs, PIL and labels are pharmaceutically acceptable.

**MAA Forms**
The MAA forms are satisfactory.

**Expert Report**
The quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
The grant of Marketing Authorisations is recommended.
III NON-CLINICAL ASPECTS

III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of cefpodoxime proxetil are well-known, no new non-clinical studies are required and none have been provided.

The applicant’s non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the product.

III.2 Pharmacology
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.3 Pharmacokinetics
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.4 Toxicology
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.5 Ecotoxicity/environmental risk assessment (ERA)
As these products are intended for substitution with products that are already marketed, no increase in environmental burden is anticipated and no Environmental Risk Assessment is necessary. A suitable justification has been provided for non-submission of an environmental risk assessment.

III.6 Discussion on the non-clinical aspects
There is no objection to the approval of these products from a non-clinical viewpoint.
IV CLINICAL ASPECTS
IV.1 Introduction
The clinical pharmacology of cefpodoxime proxetil is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamics or pharmacokinetic data are provided or are required for these applications.

IV.2 Pharmacokinetics
In support of these applications, the Marketing Authorisation Holder has submitted two bioequivalence studies:

Study 1:
A randomised, single-dose, two-period, two-treatment, two-sequence, crossover study to compare the pharmacokinetics of the test product Cefpodoxime 200 mg film-coated tablets versus the reference product Orelox 200 mg film-coated tablets (Aventis Pharma Deutschland, Germany) in healthy adult male volunteers under fasted conditions.

All volunteers received a single oral dose of either the test or the reference product with 240 ml of water under fasting conditions. Blood samples were taken for the measurement of pharmacokinetic parameters pre-dose and up to 24 hours post dose. The washout period between the two treatment arms was 11 days.

The pharmacokinetic results for cefpodoxime proxetil are presented below (ln-transformed values: geometric mean, ratios and 90% confidence intervals):

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Geometric Mean</th>
<th>Ratio (T/R)</th>
<th>90% Confidence Interval</th>
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<tr>
<td></td>
<td>Test</td>
<td>Reference</td>
<td>(%)</td>
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<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt; (µg/ml)</td>
<td>3.274</td>
<td>3.239</td>
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<td>AUC&lt;sub&gt;0-t&lt;/sub&gt; (µg/ml/hr)</td>
<td>17.681</td>
<td>17.676</td>
<td>100.03</td>
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<tr>
<td>AUC&lt;sub&gt;0-inf&lt;/sub&gt; (µg/ml/hr)</td>
<td>18.410</td>
<td>18.404</td>
<td>100.03</td>
</tr>
</tbody>
</table>

AUC<sub>0-∞</sub> area under the plasma concentration-time curve from time zero to infinity
AUC<sub>0-t</sub> area under the plasma concentration-time curve from time zero to t hours
C<sub>max</sub> maximum plasma concentration

The 90% confidence intervals for AUC and C<sub>max</sub> for test versus reference product for cefpodoxime proxetil are within predefined acceptance criteria specified in the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1). Thus, the data support the claim that the test product Cefpodoxime 200 mg film-coated tablets (Aurobindo Pharma Limited) is bioequivalent to the reference product Orelox 200 mg film-coated tablets (Aventis Pharma Deutschland, Germany).

Study 2:
A randomised, single-dose, two-period, two-treatment, two-sequence, crossover study to compare the pharmacokinetics of the test product Cefpodoxime 100 mg film-coated tablets versus the reference product Orelox 100 mg film-coated tablets (Laboratorie Aventis, France), in healthy adult male volunteers under fed conditions.
All volunteers received a single oral dose of either the test or the reference product with 240 ml of water fed conditions. Blood samples were taken for the measurement of pharmacokinetic parameters pre-dose and up to 24 hours post dose. The washout period between the two treatment arms was 8 days.

The pharmacokinetic results for cefpodoxime proxetil are presented below (ln-transformed values; geometric mean, ratios and 90% confidence intervals):

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<tr>
<th>Parameters</th>
<th>Geometric Mean</th>
<th>Ratio (T/R) (%)</th>
<th>90% Confidence Interval (%)</th>
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<tr>
<td></td>
<td>Test</td>
<td>Reference</td>
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<tr>
<td>C_{max} (µg/ml)</td>
<td>2.29</td>
<td>2.41</td>
<td>95.14</td>
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<tr>
<td>AUC_{0-t} (µg/ml/hr)</td>
<td>13.08</td>
<td>13.75</td>
<td>95.14</td>
</tr>
<tr>
<td>AUC_{0-inf} (µg/ml/hr)</td>
<td>13.41</td>
<td>14.06</td>
<td>95.40</td>
</tr>
</tbody>
</table>

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
AUC_{0-inf} area under the plasma concentration-time curve from time zero to infinity
C_{max} maximum plasma concentration

The 90% confidence intervals for AUC and C_{max} for test versus reference product for cefpodoxime proxetil are within predefined acceptance criteria specified in the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1). Thus, the data supports the claim that the test product Cefpodoxime 100 mg film-coated tablets (Aurobindo Pharma Limited) is bioequivalent to the reference product Orelox 100 mg film-coated tablets (Laboratorie Aventis, France).

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none were required for applications of this type.

IV.4 Clinical efficacy
The efficacy of cefpodoxime proxetil is well-known. No new efficacy data have been submitted and none are required for applications of this type.

IV.5 Clinical safety
With the exception of the safety data generated during the bioequivalence study, no new safety data were submitted and none are required for applications of this type. No new or unexpected safety issues were raised by the bioequivalence data.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels
The SmPCs, PIL and labels are clinically acceptable. The SmPCs are consistent with these for the originator products. The PIL is consistent with the details in the SmPCs and in-line with the current guidelines. The labelling is in-line with the current guidelines.

Clinical Overview
The clinical overview has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.
IV.6  Risk Management Plan (RMP) and Pharmacovigilance System
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Suitable justification has been provided for not submitting a risk management plan for these products.

IV.7  Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended.

V  User consultation
The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.
VI Overall conclusion, benefit/risk assessment and recommendation

QUALITY
The important quality characteristics of Cefpodoxime 100 mg and 200 mg film-coated tablets are well-defined and suitably controlled. The specifications and batch analytical results indicate batch to batch consistency. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted. As the pharmacokinetics, pharmacodynamics and toxicology of cefpodoxime proxetil are well-known, no additional data were required.

EFFICACY
With the exception of the bioequivalence studies, no new data were submitted and none are required for applications of this type. Bioequivalence has been demonstrated between the applicant’s 100 mg and 200 mg tablets and the reference product. As the 100 mg and 200 mg strengths of the product meet the criteria specified in the Notes for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98 Rev1).

SAFETY
With the exception of the safety data from the bioequivalence studies, no new data were submitted and none are required for an application of this type. No new or unexpected safety concerns arose from the bioequivalence studies.

PRODUCT LITERATURE
The SmPCs, PIL and labelling are acceptable. The SmPCs are consistent with these for the reference products. The PIL is consistent with the details in the SmPCs and in-line with the current guidelines. The labelling is in-line with the current guidelines.

BENEFIT/RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The data provided support the claim that these products can be considered equivalent to the reference products, Orelox tablets 100 mg film-coated tablets (Laboratoires Aventis, France) and Orelox 200 mg film-coated tablets (Aventis Pharma Deutschland, Germany). Extensive clinical experience with cefpodoxime proxetil is considered to have demonstrated the therapeutic value of the products. The benefit/risk is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for this medicine is located at the end of Annex 1 of this report.
# Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

<table>
<thead>
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<th>Scope</th>
<th>Procedure number</th>
<th>Product information affected</th>
<th>Date of start of the procedure</th>
<th>Date of end of procedure</th>
<th>Approval/ non approval</th>
<th>Assessment report attached Y/N (version)</th>
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</thead>
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<td>To update section 2, 4.2, 4.3, 4.6, 4.8, 5.1, 6.1, 6.6, 7 and 9 of the SmPC in line with the QRD template. Consequently the PIL and labels have been updated.</td>
<td>UK/H/1137/001-002/IB/007</td>
<td>Leaflet, SmPC and labelling.</td>
<td>12/02/2016</td>
<td>13/03/2016</td>
<td>Approved</td>
<td>Yes-see annex 1</td>
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Consequently the PIL and labels have been updated.
ANNEX 1

Our Reference: PL 16363/0336-0015
PL 16363/0337-0014

Product: Cefpodoxime 100 mg film-coated tablets
Cefpodoxime 200 mg film-coated tablets

Marketing Authorisation Holder: Milpharm Limited
Active Ingredient(s): Cefpodoxime proxetil

Type of Procedure: Mutual Recognition
Submission Type: Variation
Submission Category: Type IB
Submission Complexity: Standard
EU Procedure Number (if applicable): UK/H/1137/001-002/IB/007

Reason:
To update section 2, 4.2, 4.3, 4.6, 4.8, 5.1, 6.1, 6.6, 7 and 9 of the SmPC in line with the QRD template. Consequently the PIL and labels have been updated.

Supporting Evidence
Revised SmPC fragments, PIL and labelling.

Evaluation
The proposed changes to the SmPC, PIL and labelling are acceptable. The updated SmPC fragments and PIL have been incorporated into the Marketing Authorisations.

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The updated labelling is presented below:
Cefpodoxime 100 mg and 200 mg film-coated tablets

Cefpodoxime 200 mg film-coated tablets

Each film-coated tablet contains 260.90 mg cefpodoxime proxetil equivalent to 200 mg cefpodoxime.
Contains lactose and sunset yellow FCF (E110), see leaflet for further information.

Orol use.

Read the package leaflet before use.
Keep out of the sight and reach of children.

Store below 25°C.

PL 16363/0337

Milpharm Limited
Ares block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Cefpodoxime
#200 mg
film-coated tablets
Conclusion
Approved on 21 September 2016.