Chloramphenicol 1% w/w Eye Ointment

PL 18956/0009

UKPAR

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The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Chloramphenicol 1% w/w Eye Ointment (product licence number: PL 18956/0009) to Medicom Healthcare Ltd on 26 November 2012. This medicine is only available by prescription.

Chloramphenicol 1% w/w Eye Ointment is an antibiotic used to treat acute bacterial conjunctivitis, which is an infection of the outer surface of the eye that causes redness, discomfort and discharge from the affected eye.

Chloramphenicol 1% w/w Eye Ointment raised no clinically significant safety concerns and it was, therefore, judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.
CHLORAMPHENICOL 1% W/W EYE OINTMENT

PL 18956/0009

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted a Marketing Authorisation for the medicinal product Chloramphenicol 1% w/w Eye Ointment (PL 18956/0009) to Medicom Healthcare Ltd on 26 November 2012.

The abridged application for Chloramphenicol 1% w/w Eye Ointment was submitted under Article 10(c) of EC Directive 2001/83, last paragraph. The applicant claims that the product is identical to the reference product Chloramphenicol Eye Ointment BP (PL 18956/0005), which was licensed in the UK to Medicom Healthcare Ltd on 5 April 2006 following a change of ownership of the Marketing Authorisation. Prior to this, the reference product was licensed to FDC International Ltd, which was granted a Marketing Authorisation (PL 15872/0006) on 1 April 2000 following a change of ownership of the Marketing Authorisation from Ciba Vision Ophthalmics, which was granted the original Marketing Authorisation for the product (PL 08685/0022) on 21 November 1996.

The product contains the drug substance chloramphenicol, which is used in the treatment of bacterial conjunctivitis caused by the organisms Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfield and others.

No new data were submitted, nor was it necessary for this simple application, as the data are identical to those for the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 18956/0009
PROPRIETARY NAME: Chloramphenicol 1% w/w Eye Ointment
ACTIVE: Chloramphenicol hydrochloride
COMPANY NAME: Medicom Healthcare Ltd
LEGAL STATUS: POM

1. INTRODUCTION
This is a simple, piggyback application for Chloramphenicol 1% w/w Eye Ointment, submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Medicom Healthcare Ltd, 235 Hunts Pond Road, PO14 4PJ, UK.

The application cross-refers to Chloramphenicol Eye Ointment BP (PL 18956/0005), which was licensed in the UK to Medicom Healthcare Ltd on 5 April 2006 following a change of ownership of the Marketing Authorisation. Prior to this, the reference product was licensed to FDC International Ltd, which was granted a Marketing Authorisation (PL 15872/0006) on 1 April 2000 following a change of ownership of the Marketing Authorisation from Ciba Vision Ophthalmics, which was granted the original Marketing Authorisation for the product (PL 08685/0022) on 21 November 1996.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name
The proposed name of the product is Chloramphenicol 1% w/w Eye Ointment. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each gram of Chloramphenicol 1% w/w Eye Ointment contains 10 mg chloramphenicol (1% w/w).

The product is stored in a 4g aluminium tube and polyethylene cap.

The proposed shelf-life (48 months for product stored in an unopened container; 28 days for product once the container is first opened) and storage conditions (Do not store above 25°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available as a prescription-only medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company
The MAH is Medicom Healthcare Ltd, 235 Hunts Pond Road, PO14 4PJ, UK.
The QP responsible for pharmacovigilance is stated and a CV is included.

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

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

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

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

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

2.10 TSE Compliance
No materials of animal or human origin are included in this product. This 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 (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Carton and blister
The proposed 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 also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. From a quality perspective, a Marketing Authorisation should be granted.
**PRECLINICAL ASSESSMENT**

No new preclinical data have been supplied with this application and none is required for applications of this type.
CLINICAL ASSESSMENT

OVERVIEW
A statement has been provided confirming that the clinical particulars for Chloramphenicol 1% w/w Eye Ointment (PL 18956/0009) are identical to those for the already licensed product Chloramphenicol Eye Ointment BP (PL 18956/0005). This is satisfactory.

BIOAVAILABILITY AND BIOEQUIVALENCE
No bioequivalence study has been performed to support this application and none is needed.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSIONS
It is recommended that a Marketing Authorisation can be granted.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
Chloramphenicol 1% w/w Eye Ointment is identical to the already licensed reference product. The product is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with this application and none are required for an application of this type.

SAFETY
No new safety data have been submitted with this application and none are required for an application of this type.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, no significant preclinical or clinical safety concerns were identified, and benefit has been shown to be associated with chloramphenicol. The benefit/risk balance is therefore considered to be acceptable and a Marketing Authorisation may be granted.
## STEPS TAKEN FOR ASSESSMENT

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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation application on 28 June 2011</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 1 July 2011</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the dossier on 26 September 2011</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on the dossier on 16 March 2012</td>
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<td>5</td>
<td>Following assessment of the response the MHRA requested further information relating to the dossier on 2 August 2012</td>
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<td>6</td>
<td>The applicant responded to the MHRA’s request, providing further information on the dossier on 30 August 2012</td>
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<td>7</td>
<td>The application was determined on 26 November 2012</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

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

Label:

Chloramphenicol
1% w/w Eye Ointment

Eye ointment containing Chloramphenicol 1% w/w. Also contains Liquid Paraffin and White Petroleum.

Use as directed by the physician. Please read the enclosed leaflet carefully before use.

FOR EXTERNAL USE ONLY. STERILE UNTIL OPENED. Discard within 28 days of opening.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Store below 25°C.

PL Holder: Medicom Healthcare Ltd
235 Hunts Pond Road, Titchfield Common, Fareham, Hants PO14 4PQ, England