Chloramphenicol 1% w/w Eye Ointment

PL 31103/0021

UKPAR

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LAY SUMMARY

Chloramphenicol 1% w/w Eye Ointment

This is a summary of the Public Assessment Report (PAR) for Chloramphenicol 1% w/w Eye Ointment (PL 31103/0021). It explains how Chloramphenicol 1% w/w Eye Ointment was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Chloramphenicol 1% w/w Eye Ointment.

For practical information about using Chloramphenicol 1% w/w Eye Ointment, patients should read the package leaflet or contact their doctor or pharmacist.

What is Chloramphenicol 1% w/w Eye Ointment and what is it used for?
Chloramphenicol 1% w/w Eye Ointment contains the active ingredient chloramphenicol, which is an antibiotic. Chloramphenicol 1% w/w Eye Ointment is 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.

This medicine is identical to Klorafect 1% w/w Eye Ointment (PL 31103/0009) which is also held by the marketing authorisation holder (Blumont Pharma Limited) and was granted on 16 September 2011.

How is Chloramphenicol 1% w/w Eye Ointment used?
The recommended dose for adults, children and infants of all age groups is about 1cm of ointment to be applied into the affected eye (every three hours or more frequently if required), as directed by the patient’s doctor. The patient should continue using this ointment for at least 48 hours after their eye has got better.

The patient should always wash their hands before applying the eye ointment. The patient must take special care that the nozzle of the tube does not touch their eye, the skin around their eye or their fingers. This ointment must not be used for longer than 28 days after first opening the tube even if the tube is not empty.

Chloramphenicol 1% w/w Eye Ointment can be obtained only with a prescription. The ointment should be used exactly as advised by the doctor.

For further information on how Chloramphenicol 1% w/w Eye Ointment is used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

How does Chloramphenicol 1% w/w Eye Ointment work?
The active ingredient in this ointment is chloramphenicol. Chloramphenicol is called a bacteriostatic antibiotic which means it works by stopping the bacteria that are causing the infection from growing.

What benefits of Chloramphenicol 1% w/w Eye Ointment have been shown in studies?
The application for Chloramphenicol 1% w/w Eye Ointment is considered to be identical to the previously authorised application for Klorafect 1% w/w Eye Ointment (PL 31103/0009), with the same benefits and risks. So, no new studies have been provided for Chloramphenicol 1% w/w Eye Ointment; however, the marketing authorisation holder (Blumont Pharma Limited) has referred to their own data held for the grant of the licence for Klorafect 1% w/w Eye Ointment (PL 31103/0009) as the basis for the grant of a licence for Chloramphenicol 1% w/w Eye Ointment (PL 31103/0021).
What are the possible side effects from Chloramphenicol 1% w/w Eye Ointment?
Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects are more likely to occur than others.

Treatment with Chloramphenicol 1% w/w Eye Ointment should be stopped and the patient’s doctor should be told straight away if any of the following side effects are experienced:
• Bruising, bleeding, infections and weakness (symptoms of blood disorder).

Other possible side effects of chloramphenicol occasionally experienced are:
• Eye burning, stinging, sensitivity or visual blurring after initial application.

As with other eye preparations, the patient may occasionally experience eye burning, stinging, sensitivity or visual blurring after initial application. If this persists or increases, the patient must stop using the ointment and contact their doctor or pharmacist immediately.

For a full list of all the side effects reported with Chloramphenicol 1% w/w Eye Ointment, see section 4 of the package leaflet, available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Why is Chloramphenicol 1% w/w Eye Ointment approved?
No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Chloramphenicol 1% w/w Eye Ointment outweigh their risks; and the grant of a Marketing Authorisation (licence) was recommended.

What measures are being taken to ensure the safe and effective use of Chloramphenicol 1% w/w Eye Ointment?
A Risk Management Plan has been developed to ensure that Chloramphenicol 1% w/w Eye Ointment is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Chloramphenicol 1% w/w Eye Ointment, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Chloramphenicol 1% w/w Eye Ointment
A Marketing Authorisation was granted in the UK on 09 September 2014.

The full PAR for Chloramphenicol 1% w/w Eye Ointment follows this summary.

For more information about treatment with Chloramphenicol 1% w/w Eye Ointment, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2014.
Chloramphenicol 1% w/w Eye Ointment

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Blumont Pharma Limited a Marketing Authorisation for the medicinal product Chloramphenicol 1% w/w Eye Ointment (PL 31103/0021) on 09 September 2014. The product is a prescription-only medicine (POM) indicated in adults, children and infants of all age groups for the treatment of bacterial conjunctivitis caused by the organisms Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfeld and others.

The application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended.

Chloramphenicol 1% w/w Eye Ointment cross-refers to Kloraject 1% w/w Eye Ointment (PL 31103/0009) which was authorised to Blumont Pharma Limited on 16 September 2011. This latter product was authorised following a national informed consent application referring to Chloramphenicol Eye Ointment BP (PL 18956/0005) authorised to Medicom Healthcare Limited on 05 April 2006 following change of ownership applications from PL 15872/0006 authorised to FDC International Ltd and previously to PL 00109/0141 authorised to Roussel Laboratories Limited.

The active ingredient, chloramphenicol, is a broad spectrum antibiotic (pharmacotherapeutic group: antibiotic, ATC code: S01AA01) with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms.

No new data were submitted nor were necessary to be submitted for this application, as the data are identical to those of the previously granted cross-reference product.
1. **INTRODUCTION**

This is an abridged application for Chloramphenicol 1% w/w Eye Ointment (PL 31103/0021) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Klorafect 1% w/w Eye Ointment (PL 31103/0009) which was first granted a Marketing Authorisation in the UK on 16 November 2011 to Blumont Pharma Limited. 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**

The product is a yellowish-white eye ointment containing 1% w/w chloramphenicol.

The product is packaged into aluminium tubes with polyethylene caps containing 4 grams (g) of ointment.

The proposed shelf life for the unopened tube is 48 months which reduces to 28 days once the tube has been opened, with the storage conditions ‘Do not store above 25°C.’

The proposed packaging, shelf-life and storage conditions 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**

Blumont Pharma Limited, 23 Moortown Close, Grantham, Lincolnshire, NG31 9GG, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

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

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

2.10 TSE Compliance
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference product.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application because the proposed product is manufactured to the same formula utilising the same process as the cross-reference product, Klorafect 1% w/w Eye Ointment (PL 31103/0009).

3. EXPERT REPORT
The applicant cross-refer to the data for Klorafect 1% w/w Eye Ointment (PL 31103/0009) to which this application is claimed to be identical. This is acceptable.

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

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPCs)
The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
The Patient Information Leaflet has been prepared in line with the details registered for the cross-reference product.

User-testing of the PIL for Chloramphenicol 1% w/w Eye Ointment has been accepted based on the bridging report provided by the applicant making reference to the successful user-testing of the PIL for Klorafect 1% w/w Eye Ointment (PL 31103/0009) as the ‘parent PIL’.

Carton and label
The proposed artwork is consistent with 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. CONCLUSION
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-Clinical Assessment

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

An acceptable Risk Management Plan (RMP) has been submitted.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for the application is consistent with that previously assessed 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 for Klorafect 1% w/w Eye Ointment (PL 31103/0009) which is held by the applicant and authorised on 16 November 2011.

SAFETY
No new safety data were supplied or required for this application. Chloramphenicol has a well-established safety profile. No new or unexpected safety concerns arose from this application.

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

BENEFIT/RISK 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 chloramphenicol is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is, therefore, considered to be positive.
Chloramphenicol 1% w/w Eye Ointment

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**STEPS TAKEN FOR ASSESSMENT**

1. The MHRA received the Marketing Authorisation application on 10 December 2013.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 18 December 2013.
3. Following assessment of the application the MHRA requested further information relating to the dossier on 14 March 2014 and 22 May 2014.
4. The applicant responded to the MHRA’s request, providing further information on the 10 April 2014 and 03 July 2014.
5. The application was granted on 09 September 2014.
SUMMARY OF PRODUCT CHARACTERISTICS

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

CARTON:

TUBE: