Public Assessment Report

UK PAR

Lumecol 0.5 % w/v Eye Drops, Solution
Chloramphenicol 0.5 w/v Eye Drops, Solution

(Choramphenicol)

PL 18956/0013-0015 and 0022

Medicom Healthcare Limited
LAY SUMMARY

Lumecol 0.5 w/v Eye Drops, Solution
Chloramphenicol 0.5 w/v Eye Drops, Solution

The products may be referred to as ‘Lumecol/Chloramphenicol Eye Drops’ in this report.

This is a summary of the Public Assessment Report (PAR) for Lumecol 0.5 w/v Eye Drops, solution (PL 18956/0013) and Chloramphenicol 0.5 w/v Eye Drops, solution (PL 18956/0014-0015 and 0022). It explains how the applications for Lumecol/Chloramphenicol 0.5 w/v Eye Drops, Solution were assessed and their authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Lumecol/Chloramphenicol 0.5 w/v Eye Drops, Solution.

For practical information about using Lumecol/Chloramphenicol 0.5 w/v Eye Drops, Solution, patients should read the package leaflet or contact their doctor or pharmacist.

What are ‘Lumecol/Chloramphenicol Eye Drops’ and what are they used for?
These medicines are the same as Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK), which are already authorised in the UK. The licence holder (Medicom Healthcare Limited, UK) for Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004) has agreed that its own scientific data can be used as a basis for the grant of identical licences for Lumecol/Chloramphenicol Eye Drops (PL 18956/0013-0015 and 0022; Medicom Healthcare Limited, UK) (informed consent).

Lumecol/Chloramphenicol Eye Drops are used to treat bacterial infections that affect the front surfaces of the eye. The most common type of infection in this area is called acute bacterial conjunctivitis.

In a patient with this condition, the white part of one or both of the eyes will be red and/or the eyelids will be red or swollen. There will be a sticky discharge, which can make the eye difficult to open in the morning and the eye may feel ‘gritty’ or ‘irritated’.

Lumecol/Chloramphenicol Eye Drops are not suitable for treating eye infections that have spread to the deeper layers of the eye coverings or into the fluid within the eyeball. Antibiotic tablets or injections are needed to treat these deeper, more serious infections.

How do Lumecol/Chloramphenicol Eye Drops work?
The active substance in Lumecol/Chloramphenicol Eye Drops is chloramphenicol, which is an antibiotic.

How are Lumecol/Chloramphenicol Eye Drops used?
Lumecol/Chloramphenicol Eye Drops are available as eye drops, solution. Lumecol/Chloramphenicol Eye Drops are applied into the eye(s).

Lumecol/Chloramphenicol Eye Drops Chloramphenicol Eye Drops are recommended for use in children aged 2 years and over, in adults and the elderly. A child below the age of 2 years with an eye infection should be seen by a doctor.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.
Lumecol/Chloramphenicol Eye Drops can be obtained without a prescription at pharmacies under the supervision of a pharmacist.

What benefits of Lumecol/Chloramphenicol Eye Drops have been shown in studies?
The applications for Lumecol/Chloramphenicol Eye Drops (PL 18956/0013-0015 and 0022) are considered to be identical to the previously authorised licence for Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK), with the same benefits and risks. So, no new studies have been provided for Lumecol/Chloramphenicol Eye Drops (PL 18956/0013-0015 and 0022). However, reference is made to the studies for Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK).

What are the possible side effects from Lumecol/Chloramphenicol Eye Drops?
Like all medicines, Lumecol/Chloramphenicol Eye Drops can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Lumecol/Chloramphenicol Eye Drops, see section 4 of the package leaflet.

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

Why are Lumecol/Chloramphenicol Eye Drops approved?
No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Lumecol/Chloramphenicol Eye Drops outweigh their risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Lumecol/Chloramphenicol Eye Drops?
A Risk Management Plan has been developed to ensure that Lumecol/Chloramphenicol Eye Drops are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the package leaflets for Lumecol/Chloramphenicol Eye Drops, 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 Lumecol/Chloramphenicol Eye Drops
Marketing Authorisations were granted in the UK to Medicom Healthcare Limited on 07 February 2017.

The full PAR for Lumecol/Chloramphenicol Eye Drops follows this summary.

For more information about treatment with Lumecol/Chloramphenicol Eye Drops, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in April 2017.
Lumecol 0.5 % w/v Eye Drops, Solution
Chloramphenicol 0.5 w/v Eye Drops, Solution

(Choramphenicol)

PL 18956/0013-0015 and 0022

SCIENTIFIC DISCUSSION

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I. INTRODUCTION
The Medicines and Healthcare products Regulatory Agency (MHRA) granted Medicom Healthcare Limited Marketing Authorisations for the medicinal products for Lumecol 0.5 w/v Eye Drops, solution (PL 18956/0013) and Chloramphenicol 0.5 w/v Eye Drops, solution (PL 18956/0014-0015 and 0022) on 07 February 2017. The products are Pharmacy (P) medicines indicated for the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over.

The products may be referred to as ‘Lumecol/Chloramphenicol Eye Drops’ in this Scientific Discussion.

The applications were submitted as simple abridged (informed consent) applications according to Article 10c of Directive 2001/83/EC, as amended. Lumecol/Chloramphenicol Eye Drops cross-refer to the reference product Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK), which was authorised on 05 October 2010 following a Change of Ownership Application (COA) procedure of Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003; The Swiss Group Limited). Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003; The Swiss Group Limited) was submitted as a simple abridged application cross-referring to Chloramphenicol Eye Drops BP 0.5% w/v (PL 15872/0003; FDC International Limited), which was authorised on 16 January 1998. This reference product cross refers to PL 00109/0137 Chloramphenicol Eye Drops BP (PL 00109/0137; Roussel Laboratories Limited), which was granted on 13 December 1985.

Lumecol/Chloramphenicol Eye Drops contains the active ingredient, chloramphenicol, which is an antibiotic.

The MHRA 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.

No new non-clinical or clinical data were submitted or required for these abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended, as the data are identical to that of the previously granted cross-reference product.

II. QUALITY ASPECTS

II.1 Introduction
These are informed consent applications for Lumecol/Chloramphenicol Eye Drops (PL 18956/0013-0015 and 0022) submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications for Lumecol/Chloramphenicol Eye Drops (PL 18956/0013-0015 and 0022) cross-refer to the reference product Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK), which was authorised on 05 October 2010, following a COA procedure of Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003; The Swiss Group Limited). Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003; The Swiss Group Limited) was submitted as a simple abridged application cross-referring to Chloramphenicol Eye Drops BP 0.5% w/v (PL 15872/0003; FDC International Limited), which was authorised on 16 January 1998. This reference product cross refers to PL 00109/0137 Chloramphenicol Eye Drops BP (PL 00109/0137; Roussel Laboratories Limited), which was granted on 13 December 1985. The applications are considered valid.

II.2 DRUG SUBSTANCE
The proposed drug substance specification is consistent with the details registered for the cross-reference product.
II.3 MEDICINAL PRODUCT

Name
The proposed names of the products are Lumecol 0.5 w/v Eye Drops, solution (PL 18956/0013) and Chloramphenicol 0.5 w/v Eye Drops, solution (PL 18956/0014-0015 and 0022). The products have been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
The products consist of a bright, colourless to faint yellow aqueous eye drops solution. The eye drops contain 0.5% w/v chloramphenicol, which is equivalent to 5 mg of chloramphenicol per millilitre. The eye drops are instilled into the eyes.

The product is packaged in 10ml low density polyethylene bottles, each with a low density polyethylene dropper and high density polyethylene cap.

Legal status
The product is available as a Pharmacy (P) medicine.

Marketing Authorisation Holder/Contact Persons/Company
Medicom Healthcare Ltd, 235 Hunts Pond Road, Titchfield Common, Fareham, Hants, PO14 4PJ, UK.

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

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.

Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the respective cross-reference product.

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

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

Control of Finished Product
The proposed finished product specification is in line with the details registered for the cross reference product.

Stability of the Product
The product is sterile until opened.

The proposed shelf life for the unopened product is 24 months.

Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.
The recommended storage condition for the product is ‘Store in a refrigerator (2°C – 8°C). Keep the bottle in the outer carton in order to protect from light.’

The shelf life/storage conditions are consistent with the details registered for the cross reference product.

**Bioequivalence**

No bioequivalence data are required to support these informed consent applications, as the proposed product is manufactured to the same formula and utilising the same process as the cross-reference product.

II.4 **Discussion on chemical, pharmaceutical and biological aspects**

It is recommended that Marketing Authorisations are granted for these applications.

### III. NON-CLINICAL ASPECTS

#### III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of chloramphenicol are well-known, no new non-clinical data are required and none have been provided.

#### III.2 Pharmacology

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

#### III.3 Pharmacokinetics

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

#### III.4 Toxicology

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

#### III.5 Ecotoxicity/Environmental Risk Assessment (ERA)

The Marketing Authorisation Holder has provided suitable justification for not submitting an Environment Risk Assessment (ERA). This is consistent with the cross-reference product.

#### III.6 Discussion of the non-clinical aspects

The grant of Marketing Authorisations is recommended for Lumecol/Chloramphenicol Eye Drops.

### IV. CLINICAL ASPECTS

#### IV.1 Introduction

No new clinical data have been submitted and none are required as these are abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended. As the applications are for products that are essentially identical to the cross-reference product, this is satisfactory.

#### IV.2 Pharmacokinetics

No new data have been submitted and none are required for applications of this type. Refer to Section IV.1, Introduction, above.
IV.3 Pharmacodynamics
No new data have been submitted and none are required for applications of this type. Refer to Section IV.1, Introduction, above.

IV.4 Clinical Efficacy
No new data have been submitted and none are required for applications of this type. Refer to Section IV.1, Introduction, above.

IV.5 Clinical Safety
No new data have been submitted and none are required for applications of this type. Refer to Section IV.1, Introduction, above.

IV.6 Risk Management Plan
The MAH has submitted a Risk Management Plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to applications of this type.

A summary of safety concerns is listed in the table below:

<table>
<thead>
<tr>
<th>Summary of safety concerns</th>
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<tbody>
<tr>
<td>Important identified risks</td>
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<tr>
<td>Hypersensitivity</td>
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<tr>
<td>Myelosuppression, blood dyscrasias, aplastic anaemia</td>
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<tr>
<td>Important potential risks</td>
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<tr>
<td>Overgrowth of non-susceptible organisms</td>
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<td>Sensitisation and bacterial resistance with prolonged use</td>
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<td>Missing information</td>
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<td>Use in pregnancy and lactation</td>
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</table>

Routine pharmacovigilance and routine risk minimisation activities are acceptable to monitor the safety concerns described in the Risk Management Plan.

IV.7 Conclusion
It is recommended that Marketing Authorisations are granted, from a clinical point of view.

V. USER CONSULTATION
A final text version of the package leaflet, consistent with the leaflet for the reference product has been provided. The Marketing Authorisation Holder has committed to submitting mock-ups to the relevant regulatory authorities for approval before marketing any pack size. At the same time, the results of readability testing/readability bridging will be submitted to support the proposed leaflet. This proposal is acceptable.
VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY
The important quality characteristics of Lumecol/Chloramphenicol Eye Drops are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
The pharmacodynamics, pharmacokinetics and toxicology of chloramphenicol are well-known. No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL EFFICACY
These applications are identical to the previously granted application, Chloramphenicol Eye Drops BP 0.5% w/v/Golden Eye Antibiotic 0.5% w/v Eye Drops (PL 18956/0004; Medicom Healthcare Limited, UK).

CLINICAL SAFETY
No new data were submitted and none are required for these applications. As the safety profile of chloramphenicol is well-known, no additional safety data were required. No new or unexpected safety concerns arose from these applications.

PRODUCT LITERATURE
The SmPC, PIL and labelling are satisfactory and in line with current guidance.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. 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.

RECOMMENDATION
The grant of Marketing Authorisations is recommended
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website. The approved labelling is presented below:

Labelling for Lumecol 0.5 w/w Eye Drops, Solution (PL 18956/0013):

| PARTICULARS TO APPEAR ON THE OUTER PACKAGING |
| CARTON FOR BOTTLES(S) |

1. **NAME OF THE MEDICINAL PRODUCT**

Lumecol 0.5% w/v Eye Drops, Solution

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Chloramphenicol 0.5% w/v

For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over

3. **LIST OF EXCIPIENTS**

Other ingredients: Water for injections, Boric Acid, Borax and Phenylmercuric Nitrate

4. **PHARMACEUTICAL FORM AND CONTENTS**

Eye Drops and 10mL

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For topical administration to the eye

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops

If you do not get better within 48 hours talk to a doctor

If your eyes get worse see a doctor straight away

After 5 days, throw away any eye drops left

Contact lenses should NOT be worn for the duration of the treatment.

Contents are sterile until opened

8. **EXPIRY DATE**

EXP:
9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C).
Keep the bottle in the outer carton in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

12. MARKETING AUTHORISATION NUMBER(S)

PL 18956/0013

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

P

15. INSTRUCTIONS ON USE

For adults and children aged 2 years and over
1 drop every 2 hours for the first 48 hours and 4 hourly thereafter
To be used during waking hours only

16. INFORMATION IN BRAILLE

Chloramphenicol 0.5% w/v Eye Drops, Solution
Labelling for Chloramphenicol 0.5 w/w Eye Drops, Solution (PL 18956/0014):

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON FOR BOTTLES(S)

1. NAME OF THE MEDICINAL PRODUCT
Chloramphenicol 0.5% w/v Eye Drops, Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)
Chloramphenicol 0.5% w/v
For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over

3. LIST OF EXCIPIENTS
Other ingredients: Water for injections, Boric Acid, Borax and Phenylmercuric Nitrate

4. PHARMACEUTICAL FORM AND CONTENTS
Eye Drops and 10mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION
For topical administration to the eye

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN
Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY
Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops
If you do not get better within 48 hours talk to a doctor
If your eyes get worse see a doctor straight away
After 5 days, throw away any eye drops left
Contact lenses should NOT be worn for the duration of the treatment.
Contents are sterile until opened

8. EXPIRY DATE
EXP:
9. **SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C – 8°C).

Keep the bottle in the outer carton in order to protect from light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 18956/0014

13. **BATCH NUMBER**

LOT

14. **GENERAL CLASSIFICATION FOR SUPPLY**

P

15. **INSTRUCTIONS ON USE**

For adults and children aged 2 years and over

1 drop every 2 hours for the first 48 hours and 4 hourly thereafter

To be used during waking hours only

16. **INFORMATION IN BRAILLE**

Chloramphenicol 0.5% w/v Eye Drops, Solution
### MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS BOTTLES

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| **1.** NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION | Chloramphenicol 0.5% w/v Eye Drops, Solution  
For topical administration to the eye |
| **2.** METHOD OF ADMINISTRATION | For topical administration to the eye |
| **3.** EXPIRY DATE | EXP: |
| **4.** BATCH NUMBER | LOT |
| **5.** CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT | 10mL |
| **6.** OTHER | PL 18956/0014  
P |
Labelling for Chloramphenicol 0.5 w/w Eye Drops, Solution (PL 18956/0015):

| PARTICULARS TO APPEAR ON THE OUTER PACKAGING |
| CARTON FOR BOTTLES(S) |

1. NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 0.5% w/v Eye Drops, Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chloramphenicol 0.5% w/v

For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over

3. LIST OF EXCIPIENTS

Other ingredients: Water for injections, Boric Acid, Borax and Phenylmercuric Nitrate

4. PHARMACEUTICAL FORM AND CONTENTS

Eye Drops and 10mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration to the eye

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops

If you do not get better within 48 hours talk to a doctor

If your eyes get worse see a doctor straight away

After 5 days, throw away any eye drops left

Contact lenses should NOT be worn for the duration of the treatment.

Contents are sterile until opened

8. EXPIRY DATE

EXP:
9. **SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C – 8°C).
Keep the bottle in the outer carton in order to protect from light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

12. **MARKETING AUTHORIZATON NUMBER(S)**

PL 18956/0015

13. **BATCH NUMBER**

LOT

14. **GENERAL CLASSIFICATION FOR SUPPLY**

P

15. **INSTRUCTIONS ON USE**

For adults and children aged 2 years and over

1 drop every 2 hours for the first 48 hours and 4 hourly thereafter

To be used during waking hours only

16. **INFORMATION IN BRAILLE**

Chloramphenicol 0.5% w/v Eye Drops, Solution
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<th><strong>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</strong></th>
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<td><strong>BOTTLES</strong></td>
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<tr>
<td><strong>1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION</strong></td>
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<tr>
<td>Chloramphenicol 0.5% w/v Eye Drops, Solution</td>
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<tr>
<td>For topical administration to the eye</td>
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<tr>
<td><strong>2. METHOD OF ADMINISTRATION</strong></td>
</tr>
<tr>
<td>For topical administration to the eye</td>
</tr>
<tr>
<td><strong>3. EXPIRY DATE</strong></td>
</tr>
<tr>
<td>EXP:</td>
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<tr>
<td><strong>4. BATCH NUMBER</strong></td>
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<tr>
<td>LOT</td>
</tr>
<tr>
<td><strong>5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT</strong></td>
</tr>
<tr>
<td>10mL</td>
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<tr>
<td><strong>6. OTHER</strong></td>
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<tr>
<td>PL 18956/0015</td>
</tr>
<tr>
<td>P</td>
</tr>
</tbody>
</table>
Labelling for Chloramphenicol 0.5 w/w Eye Drops, Solution (PL 18956/0022):

1. **NAME OF THE MEDICINAL PRODUCT**

   Chloramphenicol 0.5% w/v Eye Drops, Solution

2. **STATEMENT OF ACTIVE Substance(S)**

   Chloramphenicol 0.5% w/v

   For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over

3. **LIST OF EXCIPIENTS**

   Other ingredients: Water for injections, Boric Acid, Borax and Phenylmercuric Nitrate

4. **PHARMACEUTICAL FORM AND CONTENTS**

   Eye Drops and 10mL

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

   For topical administration to the eye

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

   Keep out of the sight and reach of children

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

   Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops

   If you do not get better within 48 hours talk to a doctor

   If your eyes get worse see a doctor straight away

   After 5 days, throw away any eye drops left

   Contact lenses should NOT be worn for the duration of the treatment.

   Contents are sterile until opened

8. **EXPIRY DATE**

   EXP:
9. **SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C – 8°C).
Keep the bottle in the outer carton in order to protect from light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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PO14 4PJ, UK

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 18956/0022

13. **BATCH NUMBER**

LOT

14. **GENERAL CLASSIFICATION FOR SUPPLY**

P

15. **INSTRUCTIONS ON USE**

For adults and children aged 2 years and over
1 drop every 2 hours for the first 48 hours and 4 hourly thereafter
To be used during waking hours only

16. **INFORMATION IN BRAILLE**

Chloramphenicol 0.5% w/v Eye Drops, Solution
### MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS BOTTLES

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION</strong></td>
<td>Chloramphenicol 0.5% w/v Eye Drops, Solution For topical administration to the eye</td>
</tr>
<tr>
<td><strong>2. METHOD OF ADMINISTRATION</strong></td>
<td>For topical administration to the eye</td>
</tr>
<tr>
<td><strong>3. EXPIRY DATE</strong></td>
<td>EXP:</td>
</tr>
<tr>
<td><strong>4. BATCH NUMBER</strong></td>
<td>LOT</td>
</tr>
<tr>
<td><strong>5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT</strong></td>
<td>10mL</td>
</tr>
<tr>
<td><strong>6. OTHER</strong></td>
<td>PL 18956/0022 P</td>
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</tbody>
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Lumecol 0.5 % w/v Eye Drops, Solution
Chloramphenicol 0.5 w/v Eye Drops, Solution

(Chloramphenicol)

PL 18956/0013-0015 and 0022

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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<tbody>
<tr>
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