CHLORAMPHENICOL EYE DROPS BP 0.5% W/V
PL 23097/0003

UKPAR

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On 14th May 2010, the MHRA granted The Swiss Group Limited a Marketing Authorisation (licence) for Chloramphenicol Eye Drops BP 0.5% w/v.

Chloramphenicol Eye Drops BP 0.5% w/v contains chloramphenicol. Chloramphenicol belongs to a group of medicines called antibiotics.

Chloramphenicol Eye Drops BP 0.5% w/v is used to treat acute bacterial conjunctivitis, which is an infection of the outer surface of the eye.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits Chloramphenicol Eye Drops BP 0.5% w/v outweigh the risks; hence a Marketing Authorisation has been granted.
CHLORAMPHENICOL EYE DROPS BP 0.5% W/V
PL 23097/0003

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003) to The Swiss Group Limited on 14th May 2010. This prescription only medicine is used to treat bacterial conjunctivitis caused by the organisms Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfield and others.

This application for Chloramphenicol Eye Drops BP 0.5% w/v is submitted according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Chloramphenicol Eye Drops BP 0.5% w/v, first authorised in the UK to FDC International Limited on 16th January 1998.

The product contains the active substance chloramphenicol.

It is considered that 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.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Chloramphenicol Eye Drops BP 0.5% w/v outweigh the risks; hence Marketing Authorisations have been granted.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 23097/0003
PROPRIETARY NAME: Chloramphenicol Eye Drops BP 0.5% w/v
ACTIVE(S): Chloramphenicol
COMPANY NAME: The Swiss Group Limited
LEGAL STATUS: POM

1. INTRODUCTION
This is a simple, informed consent application for Chloramphenicol Eye Drops BP 0.5% w/v (PL 23097/0003) submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is The Swiss Group Limited, Office 1, 235 Hunts Pond Road, Titchfield Common, Fareham, Hants, PO14 4PJ, United Kingdom.

The application cross-refers to Chloramphenicol Eye Drops BP 0.5% w/v, first authorised in the UK to FDC International Limited on 16th January 1998.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Chloramphenicol Eye Drops BP 0.5% w/v. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains chloramphenicol.
The finished product is packaged in low density polyethylene bottle with polystyrene spiked cap.

The product comes in pack sizes 5ml and 10ml.

The proposed shelf-life is 24 months for the unopened product has been set with the storage precautions ‘Store in a refrigerator’ and ‘Keep the bottle in the outer carton’.
Once the product has been opened, it should be used within 28 days.
These 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 Swiss Group Limited, Office 1, 235 Hunts Pond Road, Titchfield Common, Fareham, Hants, PO14 4PJ, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of 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 for each product is 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
None of the excipients used contain material of animal or human origin.

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
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that they contain.
Labelling

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 packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.
PRECLINICAL ASSESSMENT

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

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and, as such, has been judged to be satisfactory.

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

EFFICACY
This application is identical to a previously granted application Chloramphenicol Eye Drops BP 0.5% w/v, first authorised in the UK to FDC International Limited on 16th January 1998.
No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical 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 compounds. The risk:benefit is, therefore, considered to be positive.
CHLORAMPHENICOL EYE DROPS BP 0.5% W/V  
PL 23097/0003

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<tr>
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<th>STEPS TAKEN FOR ASSESSMENT</th>
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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 24th August 2005.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 6th October 2005.</td>
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<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the quality dossier on 12th January 2006 and 16th October 2007.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 12th January 2006, 8th August 2007 and 24th March 2010 for the quality section.</td>
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<td>5</td>
<td>The application was determined on 14th May 2010.</td>
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CHLORAMPHENICOL EYE DROPS BP 0.5% W/V
PL 23097/0003

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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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Chloramphenicol Eye Drops BP 0.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Active Ingredient
Chloramphenicol 0.5g in 100ml
For excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Eye Drops

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS
Treatment of bacterial conjunctivitis caused by the organisms Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfield and others.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Recommended dosage for adults, children and infants of all age groups:- Apply 1 drop at least every 2 hours then reduce frequency as infection is controlled and continue for 48 hours after healing.

4.3 CONTRAINDICATIONS
Should not be administered to patients hypersensitive to chloramphenicol.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. The prolonged use of antibiotics may occasionally result in overgrowth of non susceptible organisms, including fungi. If any new infection appears during the treatment, the antibiotic should be discontinued and appropriate measures taken. Chloramphenicol should be reserved for use only for infections for which it is specifically indicated. Contact lenses should be removed during treatment.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Not known.

4.6 PREGNANCY AND LACTATION
Safety for use in pregnancy and lactation has not been established. Therefore, use only when considered essential by the physician.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Transient blurring of vision may occur immediately after use and driving or using machinery should not occur until the vision is clear.

4.8 UNDESIRABLE EFFECTS
May cause transient stinging. Aplastic anaemia has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of this compound. The preservative, phenylmercuric nitrate, may cause allergic reaction.

4.9 OVERDOSE
Not applicable
5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES
ATC Code: S01AA01 Ophthalmological Antiinfective Antibiotic
Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms.

5.2 PHARMACOKINETIC PROPERTIES
Not applicable to topical (ophthalmic) preparations.

5.3 PRECLINICAL SAFETY DATA
Nothing of relevance which is not included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS
Borax
Boric Acid
Phenyl Mercuric Nitrate
Purified Water

6.2 INCOMPATIBILITIES
None known

6.3 SHELF LIFE
Unopened: 24 months
Opened: 28 days

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store in a refrigerator. Keep the bottle in the outer carton.

6.5 NATURE AND CONTENTS OF CONTAINER
Low density polyethylene bottle with polystyrene spiked cap. Available in pack sizes of 5ml or 10ml.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
None stated.

7 MARKETING AUTHORISATION HOLDER
The Swiss Group Ltd
Office 1, 235 Hunts Pond Road
Titchfield Common
Fareham
Hants
PO14 4PJ
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 23097/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
14/05/2010

10 DATE OF REVISION OF THE TEXT
14/05/2010
CHLORAMPHENICOL EYE DROPS BP 0.5% W/V

Chloramphenicol 0.5% w/v
Please read this leaflet carefully before you start to take your medicine.
Keep this leaflet. You may need to read it again. If you have any further questions please ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
The medicine will be called Chloramphenicol Eye Drops in this leaflet.

In this leaflet:
1. What Chloramphenicol Eye Drops is and what it is used for
2. Before you use Chloramphenicol Eye Drops
3. How to use Chloramphenicol Eye Drops
4. Possible side effects
5. How to store Chloramphenicol Eye Drops
6. Further information

1. WHAT CHLORAMPHENICOL EYE DROPS IS AND WHAT IT IS USED FOR
Chloramphenicol belongs to a group of medicine called antibiotics. Chloramphenicol Eye Drops is used to treat acute bacterial conjunctivitis, which is an infection of the outer surfaces of the eye.

2. BEFORE YOU USE CHLORAMPHENICOL EYE DROPS
Do not use:
- If you are allergic (hypersensitive) to chloramphenicol or to any other ingredient of this medicine (see section 6.6 for more details.)
- If you have ever had problems with your bone marrow or blood when using chloramphenicol in the past.
- If you have a family history of "dyscrasias", a condition which can cause tiredness, bruising and an increased risk of infection

Take special care with Chloramphenicol Eye Drops
Please tell your doctor if you:
- Develop a new infection during this treatment
- Are wearing contact lenses

Taking other medicines
Please tell your doctor or pharmacist if you are applying any other type of eye drops or eye ointment before you start to use this medicine. Your medicine may affect their action and could alter their effect.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without any prescription.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicines. Chloramphenicol Eye Drops should not be used during pregnancy and breast-feeding unless considered essential by your doctor.

Driving and using machines
No effects on ability to drive and use machines have been reported. However do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.
3. HOW TO USE CHLORAMPHENICOL EYE DROPS

Always use Chloramphenicol Eye Drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dosage is two drops applied to the affected eye(s) every three hours for at least 48 hours, or as directed by your doctor.

If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second drop.

Instructions for use:
(please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling
- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use

Be careful not to touch the tip of the bottle on your eye or on any other surface. Ocular solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product see your doctor immediately.

If you forget to use Chloramphenicol Eye Drops

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.
4. POSSIBLE SIDE EFFECTS

Like all medicines, Chloramphenicol Eye Drops can cause side effects, although not everybody gets them.

If you experience a rare (these may affect between 1 in 1,000 and 1 in 10,000 patients) but serious allergic reaction (difficulty breathing, closing of the throat, swelling of the lips, tongue, or face or hives) to Chloramphenicol Eye Drops, stop using the medication and contact your doctor immediately.

Please tell your doctor if you notice any of the following side effects:

- Stinging, burning
- Eye irritation
- Blurring of vision

**Very rare possible side effects:** (these may affect less than 1 in 10,000 patients)
- Anaemia (in particular very low numbers of blood cells)

Some people find that their eyes sting or their sight is blurred immediately after using the drops. These effects should wear off after a short time.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

5. HOW TO STORE CHLORAMPHENICOL EYE DROPS

Keep out of the reach and sight of children
Store in a refrigerator
Store in the original package to protect from light
Discard the bottle 28 days after opening, even if there is solution remaining.
Do not use after the expiry date which is stated on the bottle and on the carton the bottle is packed in.

6. FURTHER INFORMATION

**What Chloramphenicol Eye Drops contains**
The active substance is chloramphenicol 0.5% w/v. It also contains Borax, Boric acid, Phenyl mercuric nitrate (as preservative) 0.002% w/v and purified water

**What Chloramphenicol Eye Drops looks like and contents of the pack**
Each bottle contains 5ml or 10ml of Chloramphenicol Eye Drops
Your medicine is a clear, colourless, sterile solution

**Marketing Authorisation Holder and Manufacturer**
The Swiss Group Ltd, 235 Hunts Pond Road,
Titchfield Common, Hants. PO14 4PJ

PL number: 23097/0003

Hard to see or read the leaflet? Call +44 (0) 1489 574119 for help

This leaflet was last approved in: xx/xxxx
MODE OF USE

1. Cap with a spike
   ➡️ BFS Bottle

2. Bottle as received

3. Tighten the cap on the nozzle till the cap touches the shoulder.

4. Pierced Bottle
   ➡️ The spike in the cap will pierce the tip of the bottle.

5. Tilt head backwards. Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.

6. Replace cap after every use, and screw the cap down.
## The Swiss Group

### Chloramphenicol Eye Drops BP 0.5% w/v

**Active ingredient:** chloramphenicol.  
**Preservative:** Phenylmercuric nitrate 0.0022% w/v  
Also contains borax, boric acid and water.

**For ocular use.**  
Use as directed by the Physician  
See leaflet for further information

**Keep all medicines out of the reach and sight of children**

**For external use only**

**Sterile until opened**

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**Chloramphenicol Eye Drops BP 0.5% w/v**

Store in a refrigerator.

To avoid contamination do not touch dropper tip to any surface.

Do not use the eye drops whilst wearing contact lenses.

Discard within 28 days of opening.

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**The Swiss Group Ltd**  
235 Hunts Pond Road  
Titchfield Common  
PO14 4PJ  
UK

**PL 23097/0003**
BOTTLE LABEL

The Swiss Group

Chloramphenicol Eye Drops
BP 0.5% w/v

For ocular use
Use as directed by the physician.

Keep all medicines out of the reach and sight of children

Preservative:
Phenylmercuric nitrate 0.0022% w/v

Store in a refrigerator

Store in the original package to protect from light
Discard within 28 days of opening.

5ml / 10ml

The Swiss Group Ltd
235 Hunts Pond Road
Titchfield Common
PO14 4PJ UK

PL 23097/0003