CHLORAMPHENICOL/CHLORMYTOL 1% W/W EYE OINTMENT

PL 12762/0400-1

UKPAR

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CHLORAMPHENICOL/CHLORMYTOL 1% W/W EYE OINTMENT

PL 12762/0400-1

LAY SUMMARY

On 8th June 2011, the MHRA granted Goldshield Pharmaceuticals Limited Marketing Authorisations (licences) for Chloramphenicol/Chlormytol 1% w/w Eye Ointment.

Chloramphenicol/Chlormytol 1% w/w Eye Ointment contains an antibiotic called chloramphenicol. Chloramphenicol/Chlormytol 1% w/w Eye Ointment is a topical ointment for administration to the eye only.

When chloramphenicol is given as an eye ointment, it is used to treat bacterial infections that affect the outer surfaces of the eye.

The most common type of infection in this area is called acute bacterial conjunctivitis. When you have acute bacterial conjunctivitis the white part of one or both of your eyes will be red and/or your 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’.

Chloramphenicol eye ointment is 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 and more serious infections.

Chloramphenicol 1%w/w Eye Ointment is recommended for children over 2 years, adults and the elderly.

It is recommended that any child below the age of two years with an eye infection should be seen by a doctor.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Chloramphenicol/Chlormytol 1% w/w Eye Ointment outweigh the risks; hence Marketing Authorisations have been granted.
CHLORAMPHENICOL/CHLORMYTOL 1% W/W EYE OINTMENT

PL 12762/0400-1

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted Goldshield Pharmaceuticals Limited Marketing Authorisations for the medicinal product Chloramphenicol/Chlormytol 1% w/w Eye Ointment (PL 12762/0400-1) on 8th June 2011. Chloramphenicol/Chlormytol 1% w/w Eye Ointment are supplied to the general public through pharmacies only (P) and are indicated for the treatment of acute bacterial conjunctivitis.

These applications for Chloramphenicol/Chlormytol 1% w/w Eye Ointment are submitted according to Article 10c of Directive 2001/83/EC, cross-referring to Optrex Infected Eye Ointment (PL 00062/0052), which was originally granted a licence to Optrex Limited on 30th July 2007.

Chloramphenicol is a potent inhibitor of bacterial protein synthesis, and exerts its effects by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

No new data were submitted nor were they necessary for these “simple” applications, as the data are identical to that of the previously granted cross-reference product.

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.

A satisfactory justification for the absence of a Risk Management Plan (RMP) was provided.
1. INTRODUCTION
These are “simple” applications for Chloramphenicol/Chlormytol 1% w/w Eye Ointment (PL 12762/0400-1) submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom.

These applications cross-refer to Optrex Infected Eye Ointment (PL 00062/0052), which was originally granted a licence to Optrex Limited on 30th July 2007.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed names of the product are Chloramphenicol/Chlormytol 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 contains chloramphenicol. The finished product is packaged in polyethylene tubes laminated with aluminium and fitted with a white polyethylene nozzle and screw cap containing 4g of ointment.

The proposed shelf-life for an unopened product is 4 years. After opening, the shelf-life is 28 days. It is advised to discard the medicine after a 5 day course of treatment.

The storage conditions are ‘Do not store above 25°C’.

This is consistent with the details registered for the cross-reference product.

2.3 Legal status
Pharmacy (P).

2.4 Marketing authorisation holder/Contact Persons/Company
Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom.

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

2.5 Manufacturers
The 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 composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The 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 finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The 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, which is supported by a statement from the Quality Expert.

This information is consistent with the cross-reference product.

3. EXPERT SUMMARIES
The applicant has included quality, non-clinical and clinical expert summaries in Module 2 of the applications. 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 names. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPCs)
At the time of assessment, the SmPCs are consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The patient information leaflets have been prepared in-line with the details registered for the cross-reference product. User testing results have been submitted for the PIL for Optrex Infected Eye Drops (PL 00062/0051). This is because the PIL is similar to the PIL for the cross-reference product Optrex Infected Eye Ointment (PL 00062/0052). Satisfactory bridging reports for the cross-reference product and the proposed product have been provided.

The results of consultations with target patient groups ("user testing") are 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 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 included the name of the product in Braille on the packaging and has included sufficient space for a standard UK pharmacy dispensing labels.

7. CONCLUSIONS
The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.
NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with these applications and none are required for applications of this type.

A satisfactory justification for the absence of an Environmental Risk Assessment has been provided.
CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.

A satisfactory clinical statement has been provided. The clinical summary has been provided and accepted in-line with the reference product.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for these applications are consistent with that previously approved 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
These applications are identical to the previously granted application, Optrex Infected Eye Ointment (PL 00062/0052), which was originally granted a licence to Optrex Limited on 30\textsuperscript{th} July 2007.

No new or unexpected safety concerns arise from these applications.

At the time of assessment, the SmPCs, PILs and labelling were satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT 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 risk:benefit is, therefore, considered to be positive.
CHLORAMPHENICOL/CHLORMYTOL 1% W/W EYE OINTMENT

PL 12762/0400-1

STEPS TAKEN FOR ASSESSMENT

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<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation Applications on 19th October 2007.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the applications valid on 20th December 2007.</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 3rd March 2008.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 26th March 2008 for the quality section.</td>
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<td>5</td>
<td>The applications were determined on 8th June 2011.</td>
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CHLORAMPHENICOL/CHLORMYTOL 1% W/W EYE OINTMENT

PL 12762/0400-1

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<tr>
<th>Date submitted</th>
<th>Application type</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Chlormytol 1% w/w Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Chloramphenicol 1.0% w/w.
1 g of ointment contains 10 mg chloramphenicol
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Eye ointment.
A smooth uniform translucent greasy ointment contained in a multi-laminate tube.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
Treatment of acute bacterial conjunctivitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Topical administration to the eye only.

Adults, children aged 2 years and over and elderly

The recommended dose is a small amount of ointment (~ 1cm) to be applied to the affected eye(s). The ointment should be applied either at night if eye drops are used during the day, or 3 to 4 times a day if eye ointment is used alone

The pharmacist will advise on the most suitable treatment. Treatment should continue for 5 days even if symptoms improve.

4.3 Contraindications
Chlormytol eye ointment must not be administered to:
- Patients who have a history of hypersensitivity to chloramphenicol or to any other ingredient of the ointment.
- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.
- Patients with a family history of blood dyscrasias.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported (see section 4.8).

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.

The use of topical chloramphenicol may occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the patient should be referred to the doctor.

Prolonged or frequent intermittent topical application of chloramphenicol should be avoided since it may increase the likelihood of sensitisation and emergence of resistant organisms.

Do not use for more than 5 days without consulting your doctor.

The label will state:
- If symptoms do not improve within 48 hours talk to your doctor
- Seek further immediate medical advice at any time if symptoms worsen
- Do not use if you are allergic to chloramphenicol or any of the ingredients
- Discard any remaining eye ointment after the five day course of treatment
For external use only.

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

Patients should be referred to a doctor if any of the following apply:

- Disturbed vision
- Any significant pain within the eye
- Photophobia
- Eye inflammation associated with a rash on the scalp or face
- The eye looks cloudy
- The pupil looks unusual
- Suspected foreign body in the eye

Patients should also be referred to their doctor if any of the following in his/her medical history apply:

- Previous conjunctivitis in the recent past
- Glaucoma
- Dry eye syndrome
- Eye surgery or laser treatment in the last 6 months
- Eye injury
- Current use of other eye drops or eye ointment

If you wear contact lenses, seek advice either from your optometrist, contact lens practitioner or doctor before you use this product. You should not wear your contact lenses during the course of treatment. If you wear soft contact lenses do not start wearing them for at least 24 hours after you have finished using the eye ointment.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Bone marrow depressant drugs

4.6 PREGNANCY AND LACTATION

The safety of Chlormytol eye ointment during pregnancy and lactation has not been established. As this product is for sale without prescription it is not recommended for use during pregnancy.

In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be avoided.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Blurring of vision can occur with the ointment and patients should be warned not to drive or operate machinery unless their vision is clear.

4.8 UNDESIRABLE EFFECTS

Transient burning or stinging sensations may occur with the use of chlormytol eye ointment. Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

4.9 Overdose

In view of the relatively small amount of chloramphenicol in chlormytol eye ointment, overdosage with this product is unlikely to constitute a hazard.

If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If symptoms persist after this, an ophthalmological examination should be considered.
5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: D06AX02

Chloramphenicol is a potent inhibitor of bacterial protein synthesis, and exerts its effects by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax anenfeld, Klebsiella/Enterobacter species and others. Entrobacteriaceae are variably resistant while Pseudomonas and Mycobacteria are usually resistant.

5.2 PHARMACOKINETIC PROPERTIES

Chloramphenicol enters the aqueous humour following topical application.

Chloramphenicol is widely distributed in body tissues and fluids: it enters the CSF, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the fetal circulation, into breast milk, and into the aqueous and vitreous humour of the eye. Up to about 60% in the circulation is bound to plasma protein. The half-life of chloramphenicol has been reported to range from 1.5 to 4 hours; the half-life is prolonged in patients with severe hepatic impairment and is also much longer in neonates. Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites. Chloramphenicol is excreted mainly in urine.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetic in a given patient.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Liquid Paraffin
Polyethylene in Mineral Oil (Plastibase 50W)

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

Unopened: 4 years
After first opening: 28 days

Although the shelf life once opened is 28 days, patients will be advised to discard the medicine after a 5 day course of treatment.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Supplied in a polyethylene tube laminated with aluminium and fitted with a white polyethylene nozzle and screw cap containing 4g of ointment.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

None

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Limited,
NLA Tower, 12-16 Addiscombe Road,
Croydon, Surrey, CR0 0XT, United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 12762/0400

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
08/06/2011

10 DATE OF REVISION OF THE TEXT
08/06/2011
1 NAME OF THE MEDICINAL PRODUCT
Chloramphenicol 1% w/w Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Chloramphenicol 1.0% w/w.
1 g of ointment contains 10 mg chloramphenicol
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Eye ointment.
A smooth uniform translucent greasy ointment contained in a multi-laminate tube.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
Treatment of acute bacterial conjunctivitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Topical administration to the eye only.

Adults, children aged 2 years and over and elderly

The recommended dose is a small amount of ointment (~ 1cm) to be applied to the affected eye(s). The ointment should be applied either at night if eye drops are used during the day, or 3 to 4 times a day if eye ointment is used alone.

The pharmacist will advise on the most suitable treatment. Treatment should continue for 5 days even if symptoms improve.

4.3 Contraindications
Chloramphenicol 1% w/w eye ointment must not be administered to:
- Patients who have a history of hypersensitivity to chloramphenicol or to any other ingredient of the ointment.
- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.
- Patients with a family history of blood dyscrasias.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported (see section 4.8).

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.

The use of topical chloramphenicol may occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the patient should be referred to the doctor.

Prolonged or frequent intermittent topical application of chloramphenicol should be avoided since it may increase the likelihood of sensitisation and emergence of resistant organisms.

Do not use for more than 5 days without consulting your doctor.

The label will state:
- If symptoms do not improve within 48 hours talk to your doctor
- Seek further immediate medical advice at any time if symptoms worsen
- Do not use if you are allergic to chloramphenicol or any of the ingredients
- Discard any remaining eye ointment after the five day course of treatment

For external use only.
Keep all medicines out of the sight and reach of children.

Patients should be referred to a doctor if any of the following apply:

- Disturbed vision
- Any significant pain within the eye
- Photophobia
- Eye inflammation associated with a rash on the scalp or face
- The eye looks cloudy
- The pupil looks unusual
- Suspected foreign body in the eye

Patients should also be referred to their doctor if any of the following in his/her medical history apply:

- Previous conjunctivitis in the recent past
- Glaucoma
- Dry eye syndrome
- Eye surgery or laser treatment in the last 6 months
- Eye injury
- Current use of other eye drops or eye ointment

If you wear contact lenses, seek advice either from your optometrist, contact lens practitioner or doctor before you use this product. You should not wear your contact lenses during the course of treatment. If you wear soft contact lenses do not start wearing them for at least 24 hours after you have finished using the eye ointment.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Bone marrow depressant drugs

4.6 PREGNANCY AND LACTATION

The safety of Chloramphenicol 1% w/w eye ointment during pregnancy and lactation has not been established. As this product is for sale without prescription it is not recommended for use during pregnancy.

In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be avoided.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Blurring of vision can occur with the ointment and patients should be warned not to drive or operate machinery unless their vision is clear.

4.8 UNDESIRABLE EFFECTS

Transient burning or stinging sensations may occur with the use of Chloramphenicol 1% w/w eye ointment. Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

4.9 Overdose

In view of the relatively small amount of chloramphenicol in Chloramphenicol 1% w/w eye ointment, overdosage with this product is unlikely to constitute a hazard.

If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If symptoms persist after this, an ophthalmological examination should be considered.
5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: D06AX02

Chloramphenicol is a potent inhibitor of bacterial protein synthesis, and exerts its effects by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax anenfeld, Klebsiella/Enterobacter species and others. Enterobacteriaceae are variably resistant while Pseudomonas and Mycobacteria are usually resistant.

5.2 PHARMACOKINETIC PROPERTIES

Chloramphenicol enters the aqueous humour following topical application.

Chloramphenicol is widely distributed in body tissues and fluids: it enters the CSF, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the fetal circulation, into breast milk, and into the aqueous and vitreous humour of the eye. Up to about 60% in the circulation is bound to plasma protein. The half-life of chloramphenicol has been reported to range from 1.5 to 4 hours; the half-life is prolonged in patients with severe hepatic impairment and is also much longer in neonates. Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites. Chloramphenicol is excreted mainly in urine.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetic in a given patient.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Liquid Paraffin
Polyethylene in Mineral Oil (Plastibase 50W)

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

Unopened: 4 years
After first opening: 28 days

Although the shelf life once opened is 28 days, patients will be advised to discard the medicine after a 5 day course of treatment.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Supplied in a polyethylene tube laminated with aluminium and fitted with a white polyethylene nozzle and screw cap containing 4g of ointment.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

None

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey,
MARKETING AUTHORISATION NUMBER(S)
PL 12762/0401

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
08/06/2011

DATE OF REVISION OF THE TEXT
08/06/2011
PATIENT INFORMATION LEAFLET

Chlormytol 1% w/w Eye Ointment
(Chloramphenicol)

Please read all of this leaflet carefully before you start using your eye ointment. Keep this leaflet. You may need to read it again.
Remember – this medicine is for you. Never give it to other people – it may harm them, even if their symptoms appear to be the same.

1. WHAT IS YOUR MEDICINE FOR?
Chlormytol 1% w/w Eye Ointment is a topical ointment for administration to the eye only, it contains an antibiotic called chloramphenicol. When chloramphenicol is given in eye ointment, it is used to treat bacterial infections that affect the outer surfaces of the eye.
The most common type of infection in this area is called acute bacterial conjunctivitis. When you have acute bacterial conjunctivitis the white part of one or both of your eyes will be red and /or your 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 eyes ring gritty. (Please note: chloramphenicol eye ointment is 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 and more serious infections.

2. BEFORE USING YOUR MEDICINE
Chlormytol 1% w/w Eye Ointment is recommended for children over 2 years, adults and the elderly. It is recommended that any child below the age of two years with an eye infection should be seen by a doctor.
Do not use this product if you:
• are allergic to chloramphenicol or any of the ingredients shown under section 6 “What is in the pack”
• have ever had problems with your blood (in particular with low numbers of cells) during previous treatments with chloramphenicol
• have a family history of blood problems such as low white blood cell, red blood cell or platelet count.
Do not use this product and seek advice from a doctor if:
• your eyesight is affected (loss of sight, reduced vision, blurred vision or halos around lights)
• you have pain within the eye
• your eye has suffered a blow or other injury
• your eye is inflamed and you have a rash on the scalp or face
• the pupil of your eye looks unusual or your eye looks cloudy
• your eyes are sensitive to light
• you have (or think you have) a foreign body in your eye, which has not been removed
• you have recently had an eye infection
• you suffer from or have ever suffered from glaucoma or dry eye syndrome
• you wear contact lenses. If you wear contact lenses and your contact lens practitioner or doctor has advised you to use this product, do not wear your lenses during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment
• you are using any other eye drops or eye ointment
• you have had eye surgery or laser treatment in the last 6 months.
Tell your pharmacist before using this product if you:
• are taking any other medicines
• suffer from any other eye problems.
If you are taking other medicines:
If you are taking bone marrow depressant drugs (drugs which decrease the activity of the bone marrow, causing low blood cell counts) such as azathioprine or receiving chemotherapy, seek the advice of your pharmacist or your doctor before using this product.
Pregnancy and Breastfeeding:
If you are pregnant, planning to become pregnant or breastfeeding tell your doctor or pharmacist before using this product.
Driving and operating machinery:
After using the eye ointment, you may temporarily get blurred vision. Do not drive or operate machinery until your vision is clear. If in doubt, talk to your pharmacist or doctor.

3. HOW TO USE
Applying the ointment:
To be used in the eye(s) only.
1. Check the tube seal is not broken before first using the eye ointment.
2. Wash and dry your hands.
3. Remove the cap. Take special care that the nozzle of the tube does not touch your eye, the skin around your eye or your fingers.
4. Use a mirror, this will help you see what you are doing.
5. Place the nozzle of the tube close to your eye. Gently pull the lower eyelid downwards and look up.
6. Squeeze the tube gently and apply about 1cm of the ointment to the space between the lower eyelid and the eye.
7. Close for a moment.
8. When both eyes are to be treated, repeat steps 5-7.
9. Replace the cap securely after use.

Whilst applying the ointment, do not
- Breathe on or touch the nozzle of the tube
- Touch the eyes or eyelids with the nozzle of the tube
- Share your ointment with anyone else.

For external use only

Dose:
The dose is a small amount of ointment (approx 1cm) to be applied to the affected eye(s) if you are using drops during the day and the ointment at night - apply the ointment at night, before going to bed. If you are using just the ointment - apply 3 to 4 times a day.

Length of treatment:
The course of treatment is 5 days. Keep using the eye ointment for 5 days, do not stop just because you feel better - this could make your condition worse. If your symptoms do not improve within 48 hours, consult your doctor. If your symptoms get worse, seek medical advice at once.

Do not use Chloromyl 1% w/w Eye Ointment for more than 5 days without consulting your doctor. Discard any remaining ointment after the 5 day course of treatment.

If you forget to use your ointment:
If you have only just missed a dose and it is a long time before the next dose is due, put in the missed dose straight away. If you have missed the dose some time ago and it is nearly time for your next dose, just put in the next dose of ointment at the right time. Never double up on a next dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS
Some people may get one or more of these side effects. Some effects happen straight away but do not last long – others may only happen after several days of use.

Possible side effects include:
- allergic effects such as itching, or rashes (get medical help straight away if you get a severe reaction with swelling or breathing problems)
- changes in the blood (anaemia) leading to severe tiredness or easy bruising.
Stop using the treatment and consult your doctor if you experience these effects.
- the use of topical chloramphenicol may occasionally result in the overgrowth of other non susceptible organisms including fungi. If any new infection appears during treatment you should tell your doctor
- blurred vision or mild burning or stinging when you put the ointment in. These should subside quickly. If you do not feel well, or are worried about your health, talk to a pharmacist or doctor. If any of the side effects gets serious or if you experience any side effect not listed in this leaflet please tell your doctor or pharmacist.

5. STORING YOUR MEDICINE
Replace the cap securely after use. Do not store above 25°C.
Keep all medicines out of the sight and reach of children. If your doctor tells you to stop treatment, return any leftover ointment to your pharmacist. Do not use after the ‘use by’ date shown on the tube and end of the carton. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment. The contents of the tube must be used within 28 days after opening. After 28 days any remaining product must be discarded.

6. WHAT IS IN THE PACK?
Each pack contains 4g of the ointment. The ointment contains 1%/w/w chloramphenicol, which is equivalent to 10mg of chloramphenicol per 1 gram of ointment. Also contains liquid paraffin and polyethylene in mineral oil.

Further information:
If you have any questions or are not sure about anything, ask your pharmacist or doctor. They can obtain more information about this medicine if needed.

Product Licence Holder: Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK.
Manufacturer: Patheon UK Limited, Kingfisher Drive, Covingham, Swindon, Wiltshire SN3 5BZ, UK.
PL 12762/0400
Leaflet revised May 2011 XXXXX/LF/A
PATIENT INFORMATION LEAFLET
Chloramphenicol
1% w/w Eye Ointment

Please read all of this leaflet carefully before you start using your eye ointment. Keep this leaflet. You may need to read it again. Remember – this medicine is for you. Never give it to other people – it may harm them, even if their symptoms appear to be the same.

1. WHAT IS YOUR MEDICINE FOR?
Chloramphenicol 1% w/w Eye Ointment is a topical ointment for administration to the eye only, it contains an antibiotic called chloramphenicol. When chloramphenicol is given in eye ointment, it is used to treat bacterial infections that affect the outer surfaces of the eye.
The most common type of infection in this area is called acute bacterial conjunctivitis. When you have acute bacterial conjunctivitis the white part of one or both of your eyes will be red and/or your 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”. Chloramphenicol eye ointment is 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 and more serious infections.

2. BEFORE USING YOUR MEDICINE
Chloramphenicol 1% w/w Eye Ointment is recommended for children over 2 years, adults and the elderly. It is recommended that any child below the age of two years with an eye infection should be seen by a doctor.
Do not use this product if you:
- are allergic to chloramphenicol or any of the ingredients shown under section 6 “What is in the pack”
- have ever had problems with your blood (in particular with low numbers of cells) during previous treatments with chloramphenicol
- have a family history of blood problems such as low white blood cell, red blood cell or platelet count.
Do not use this product and seek advice from a doctor if:
- your eyesight is affected (loss of sight, reduced vision, blurred vision or halos around lights)
- you have pain within the eye
- your eye has suffered a blow or other injury
- your eye is inflamed and you have a rash on the scalp or face
- the pupil of your eye looks unusual or your eye looks cloudy
- your eyes are sensitive to light
- you have (or think you have) a foreign body in your eye, which has not been removed
- you have recently had an eye infection
- you suffer from or have ever suffered from glaucoma or dry eye syndrome
- you wear contact lenses. If you wear contact lenses and your contact lens practitioner or doctor has advised you to use this product, do not wear your lenses during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment
- you are using any other eye drops or eye ointment
- you have had eye surgery or laser treatment in the last 6 months.
Tell your pharmacist before using this product if you:
- are taking any other medicines
- suffer from any other eye problems.

If you are taking other medicines:
If you are taking bone marrow depressant drugs (drugs which decrease the activity of the bone marrow, causing low blood cell counts) such as azathioprine or receiving chemotherapy, seek the advice of your pharmacist or your doctor before using this product.

Pregnancy and Breastfeeding:
If you are pregnant, planning to become pregnant or breastfeeding tell your doctor or pharmacist before using this product.

Driving and operating machinery:
After using the eye ointment, you may temporarily get blurred vision. Do not drive or operate machinery until your vision is clear. If in doubt, talk to your pharmacist or doctor.

3. HOW TO USE
Applying the ointment:
To be used in the eye(s) only.
1. Check the tube seal is not broken before first using the eye ointment.
2. Wash and dry your hands.
3. Remove the cap. Take special care that the nozzle of the tube does not touch your eye, the skin around your eye or your fingers.
4. Use a mirror, this will help you see what you are doing.
5. Place the nozzle of the tube close to your eye. Gently pull the lower eyelid downwards and look up.
6. Squeeze the tube gently and apply about 1cm of the ointment to the space between the lower eyelid and the eye.
7. Close for a moment.
8. When both eyes are to be treated, repeat steps 5-7.
9. Replace the cap securely after use.

Whilst applying the ointment, do not
- Breathe on or touch the nozzle of the tube
- Touch the eyes or eyelids with the nozzle of the tube
- Share your ointment with anyone else.

For external use only

Dose:
The dose is a small amount of ointment (approx 1cm) to be applied to the affected eye(s).
If you are using drops during the day and the ointment at night - apply the ointment at night, before going to bed.
If you are using just the ointment – apply 3 to 4 times a day.

Length of treatment:
The course of treatment is 5 days. Keep using the eye ointment for 5 days, do not stop just because you feel better – this could make your condition worse.
If your symptoms do not improve within 48 hours, consult your doctor. If your symptoms get worse, seek medical advice at once.

Do not use Chloramphenicol 1% w/w Eye Ointment for more than 5 days without consulting your doctor.
Discard any remaining ointment after the 5 day course of treatment.

If you forget to use your ointment
If you have only just missed a dose and it is a long time before the next dose is due, put in the missed dose straight away. If you have missed the dose some time ago and it is nearly time for your next dose, just put in the next dose of ointment at the right time. Never double up on a next dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS

Some people may get one or more of these side effects. Some effects happen straight away but do not last long – others may only happen after several days of use.

Possible side effects include:
- allergic effects such as itching, or rashes (get medical help straight away if you get a severe reaction with swelling or breathing problems)
- changes in the blood (anaemia) leading to severe tiredness or easy bruising.

Stop using the treatment and consult your doctor if you experience these effects.
- the use of topical chloramphenicol may occasionally result in the overgrowth of other non susceptible organisms including fungi. If any new infection appears during treatment you should tell your doctor
- blurred vision or mild burning or stinging when you put the ointment in. These should subside quickly.
If you do not feel well, or are worried about your health, talk to a pharmacist or doctor. If any of the side effects gets serious or if you experience any side effect not listed in this leaflet please tell your doctor or pharmacist.

5. STORING YOUR MEDICINE

Replace the cap securely after use. Do not store above 25°C.

Keep all medicines out of the sight and reach of children. If your doctor tells you to stop treatment, return any leftover ointment to your pharmacist. Do not use after the ‘use by’ date shown on the tube and end of the carton.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment. The contents of the tube must be used within 28 days after opening. After 28 days any remaining product must be discarded.

6. WHAT IS IN THE PACK?

Each pack contains 4g of the ointment. The ointment contains 1% w/w chloramphenicol, which is equivalent to 10mg of chloramphenicol per 1 gram of ointment. Also contains liquid paraffin and polyethylene in mineral oil.

Further information:
If you have any questions or are not sure about anything, ask your pharmacist or doctor. They can obtain more information about this medicine if needed.

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Manufacturer: Patheon UK Limited, Kingfisher Drive, Coggingham, Swindon, Wiltshire SN3 5BZ, UK.
PL 12762/0400.
Leaflet revised: May 2011 XXXXX/LF/A
Chloramphenicol
1% w/w Eye Ointment

Treatment of Acute Bacterial Conjunctivitis
Contains chloramphenicol 1%w/w
Read the enclosed leaflet before use.
Dose: About 1cm of ointment in the affected eye 3-4 times daily for 5 days. Use once daily, at night, if also using Chloramphenicol eye drops. Seek immediate medical advice at any time if symptoms worsen.

FOR EXTERNAL USE ONLY
PL 12762/0401 P XXXX/TU/B
Goldshield Pharmaceuticals Ltd. 4g

Chlormytol
1% w/w Eye Ointment

Chloramphenicol

Treatment of Acute Bacterial Conjunctivitis
Contains chloramphenicol 1%w/w
Read the enclosed leaflet before use.
Dose: About 1cm of ointment in the affected eye 3-4 times daily for 5 days. Use once daily, at night, if also using Chloramphenicol eye drops. Seek immediate medical advice at any time if symptoms worsen.

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