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CHLORAMPHENICOL 1% W/W ANTIBIOTIC EYE OINTMENT
(CHLORAMPHENICOL)

PL 16028/0133-4

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Galpharm Healthcare Limited Marketing Authorisations (licences) for the medicinal product Chloramphenicol 1% w/w antibiotic eye ointment (PL 16028/0133-4) on 5th November 2009. This is a P licensed medicine available only from pharmacies, under the supervision of a pharmacist.

Chloramphenicol belongs to a group of medicines called antibiotics. Antibiotics are used for infections caused by bacteria. Chloramphenicol eye ointment is for simple eye infections called “acute bacterial conjunctivitis”. This is sometimes known as “red eye” because the white part of the affected eye(s) will be red and/or the eyelid(s) will be red or swollen. There may also be a sticky discharge which can make the eye difficult to open in the morning, and the eye may feel ‘gritty’ or ‘irritated’.

These applications are duplicates of a previously granted application for Chloramphenicol Eye Ointment B.P. 1% w/w (PL 00156/0105), authorised to Martindale Pharmaceuticals Limited on 18th September 2007.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using Chloramphenicol 1% w/w antibiotic eye ointment outweigh the risk; hence Marketing Authorisations have been granted.
CHLORAMPHENICOL 1% W/W ANTIBIOTIC EYE OINTMENT
(CHLORAMPHENICOL)
PL 16028/0133-4

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Galpharm Healthcare Limited Marketing Authorisations for the medicinal product Chloramphenicol 1% w/w antibiotic eye ointment (PL 16028/0133-4) on 5th November 2009. This is a P licensed medicine available only from pharmacies.

These applications were submitted as simple abridged ‘informed consent’ applications according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Chloramphenicol Eye Ointment B.P. 1% w/w (PL 00156/0105), authorised to Martindale Pharmaceuticals Limited on 18th September 2007.

Chloramphenicol is a broad spectrum antibiotic which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis* (formerly known as *Branhamella catarrhalis*) particularly in children.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus*, and streptococci such as *Str. pneumoniae*, *Str. pyogenes*, and the viridans streptococci. Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

Evidence suggests that chloramphenicol is absorbed systemically via topical ocular administration. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces.

Justification has been provided for absence of an Environmental Risk Assessment. It is accepted that the drug product will not pose additional environmental risk.

No new data were submitted nor was it necessary for these simple applications, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.
PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER: PL 16028/0133-4

PROPRIETARY NAME: Chloramphenicol 1% w/w antibiotic eye ointment

ACTIVE INGREDIENT/S: Chloramphenicol

COMPANY NAME: Galpharm Healthcare Limited

E.C. ARTICLE: Article 10c of Directive 2001/83/EC (as amended)

LEGAL STATUS: P

1. INTRODUCTION

These are simple abridged applications, submitted under Article 10c of Directive 2001/83/EC (as amended) for Chloramphenicol 1% w/w antibiotic eye ointment. The proposed MA holder is ‘Galpharm Healthcare Limited’.

The reference product is Chloramphenicol Eye Ointment B.P. 1% w/w (PL 00156/0105), held by Martindale Pharmaceuticals Limited. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the products is Chloramphenicol 1% w/w antibiotic eye ointment. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Chloramphenicol 1% w/w antibiotic eye ointment is a smooth yellow ointment for ocular use. The eye ointment contains Chloramphenicol 1% w/w. The eye drops are licensed for marketing in pre-printed collapsible polyethylene / aluminium foil laminated tubes with integral nozzles and tamper evident polyethylene caps. Each tube is packed into a carton with a patient information leaflet.

The approved shelf-life (36 months unopened, 28 days opened) and storage conditions (‘Do not store above 25°C.’) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a P licensed medicine available only from pharmacies, under the supervision of a pharmacist

2.4 Marketing authorisation holder / Contact Persons / Company

The proposed Marketing Authorisation holder is ‘Galpharm Healthcare Ltd, Hugh House, Dodworth Business Park, Barnsley, South Yorkshire S75 3SP’.

The QP responsible for pharmacovigilance was stated and their CV included.
2.5 Manufacturers
The proposed manufacturing site is consistent with that 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 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
No materials of animal or human origin are included in the product.

3. EXPERT REPORTS
Satisfactory expert reports and curriculum vitae of experts were provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product (smooth yellow ointment) is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The approved SmPCs are consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON
PIL
The patient information leaflet has been prepared in the user tested format and in line with the details registered for the cross-reference product. The approved PIL is satisfactory.
Labelling

Colour mock-ups of the labelling have been provided and are satisfactory. The approved 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 products in Braille on the outer packaging.

7. CONCLUSIONS

The grounds for these applications are considered adequate. Marketing Authorisations were, therefore, granted.
PRECLINICAL ASSESSMENT

These applications were submitted as simple abridged applications according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with these applications and none are required for applications of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.
CLINICAL ASSESSMENT

These applications were submitted as simple abridged applications according to article 10c of Directive 2001/83/EC (as amended).

As these are duplicate applications for PL 00156/0105, no new clinical data have been supplied with the applications, and none are required for applications of this type. A clinical expert report has been written by a suitably qualified person and is satisfactory.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for these applications are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

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

EFFICACY
These applications are identical to the previously granted application for Chloramphenicol Eye Ointment B.P. 1% w/w (PL 00156/0105, Martindale Pharmaceuticals Limited).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPCs, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

Package leaflets have 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 leaflets are well-structured and organised, easy to understand and written in a comprehensive manner. The testing shows that patients/users are able to act upon the information that the leaflets contain.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging.

RISK BENEFIT ASSESSMENT
The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference product. The risk: benefit is considered to be positive.
CHLORAMPHENICOL 1% W/W ANTIBIOTIC EYE OINTMENT
(CHLORAMPHENICOL)

PL 16028/0133-4

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the marketing authorisation applications on 15th September 2008

2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 24th September 2008

3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 19th June 2009

4. The applicant responded to the MHRA’s request, providing further information for the quality sections on 26th June 2009

5. The applications were determined on 5th November 2009
CHLORAMPHENICOL 1% W/W ANTIBIOTIC EYE OINTMENT
(CHLORAMPHENICOL)

PL 16028/0133-4

STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Chloramphenicol 1% w/w antibiotic eye ointment / Goldeneye Chloramphenicol 1% w/w antibiotic eye ointment (PL 16028/0133 & 0134) is as follows. The differences are highlighted:

1 NAME OF THE MEDICINAL PRODUCT

PL 16028/0133 - Chloramphenicol 1% w/w Antibiotic Eye Ointment / Goldeneye Chloramphenicol 1% w/w Antibiotic Eye Ointment

PL 16028/0134 - Chloramphenicol 1% w/w Antibiotic Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 1% w/w
Excipient(s): Also contains wool fat.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Ointment
Smooth yellow ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Treatment of acute bacterial conjunctivitis.

4.2 Posology and method of administration
Administration: For topical ocular use.
The ointment is applied into the space between the lower eyelid and the eye.
Adults (including elderly people) and children aged 2 years and over:
If using just the eye ointment, apply about 1 cm of ointment to the affected eye(s) 3 to 4 times a day.
If using chloramphenicol eye drops during the day and the eye ointment at night - apply the ointment at night, before going to bed.
The course of treatment is 5 days.

4.3 Contraindications
Hypersensitivity to chloramphenicol or to any of the ingredients.
Family or personal history of blood dyscrasia including aplastic anaemia.

4.4 Special warnings and precautions for use
The eye ointment should not be used in children under the age of 2, since there have been very rare reports of leukemia and grey baby syndrome.
Prolonged use of chloramphenicol ointment is not advisable. Chloramphenicol eye ointment should not be used for more than 5 days at a time except on the advice of a doctor.
The label will state:
• Consult your doctor immediately if:
• symptoms worsen at any time
• no improvement within 48 hours.

• Discard after a 5 day course of treatment.
• Do not use if allergic to:
  o chloramphenicol
  o the other ingredients

Chloramphenicol eye ointment should not be recommended under the following circumstances (in these circumstances patients should be referred to their doctor):

• Severe pain within the eye
• Disturbed vision
• Photophobia
• The pupil looks unusual
• The eye looks cloudy
• Associated pain or swelling around the eye or face
• The patient has had conjunctivitis previously in the recent past
• The patient has glaucoma
• The patient has dry eye syndrome
• The patient has an eye injury
• Suspected foreign body in the eye
• The patient is already using other eye ointments or eye drops
• The patient has had eye surgery or laser treatment in the last 6 months

If you wear contact lenses, seek advice either from your contact lens practitioner (optician, optometrist) 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 the eye ointment.

The product contains wool fat (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

4.6 Pregnancy and lactation

Chloramphenicol may be absorbed systemically following the use of the eye ointment. Chloramphenicol does cross the placenta and enter breast milk. Therefore chloramphenicol eye ointment should not be used during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation of the ointment. User should not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Local effects:

Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis have been reported.
Systemic effects:

Very rarely cases of major adverse hematological events (bone marrow depression, aplastic anaemia and death) have been reported following ocular use of chloramphenicol.

4.9 Overdose

Refer to a doctor in the event of accidental ingestion of the eye ointment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (A1C code): S01 AA01, antibiotics for topical use.

Chloramphenicol is a broad spectrum antibiotic which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis* (formerly known as *Branhamella catarrhalis*) particularly in children.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus*, and streptococci such as *Str. pneumoniae*, *Str. pyogenes*, and the viridans streptococci.

Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

5.2 Pharmacokinetic properties

Evidence suggests that chloramphenicol is absorbed systemically via topical ocular administration. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, is secreted in saliva, with the highest concentrations occurring in the kidneys and liver.

Chloramphenicol also diffuses across the placenta into the foetal circulation and into breast milk.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half life of 1.5 to 5 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours in the latter.

5.3 Preclinical safety data

No additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin, wool fat, yellow soft paraffin.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months unopened
28 days once opened
6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
Pre-printed collapsible polyethylene / aluminium foil laminated tube with integral nozzle and a tamper evident polyethylene cap. Each tube is packed into a carton.
Contents: 4g of product.

6.6 Special precautions for disposal
Sterile until opened.
Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.

7 MARKETING AUTHORISATION HOLDER
Galpharm Healthcare Ltd
Hugh House
Dodworth Business Park
Barnsley
South Yorkshire
S75 3SP

8 MARKETING AUTHORISATION NUMBER(S)
PL 16028/0133
PL 16028/0134

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
05/11/2009

10 DATE OF REVISION OF THE TEXT
05/11/2009
PRODUCT INFORMATION LEAFLET

Chloramphenicol 1% w/w
Antibiotic Eye Ointment

Patient information leaflet

Read all the leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms get worse or do not improve.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

1. What your medicine is and what it is used for

Chloramphenicol belongs to a group of medicines called antibiotics. Antibiotics are used for infections caused by bacteria. Chloramphenicol eye ointment is for simple eye infections called "acute bacterial conjunctivitis". This is sometimes known as "red eye" because the white part of the affected eye(s) will be red and/or the eyelid(s) will be red or swollen. There may also be a sticky discharge which can make the eye difficult to open in the morning, and the eye may feel "gritty" or irritated.

2. Before you use your medicine

Do not use the ointment and talk to your doctor or pharmacist if:
- You are allergic to chloramphenicol or anything else in the ointment. Everything in the ointment is listed in Section 6 "Further Information".
- You or a member of your family has had problems with their blood or bone marrow. These problems can include a severe reduction in red blood cells or lower than normal blood count.
- The person needing to use the ointment is under 2 years of age.

Do not use the ointment and talk to your doctor or pharmacist straight away if any of the following apply to you:
- Your eye is painful (rather than just feeling sore or gritty) or you have pain or swelling around the eye or face.
- Your sight is affected by loss of vision, reduced or blurred vision or you see halos around lights.
- It is too painful to open your eyes properly.
- Your pupil (the black circle in the centre of your eye) looks different. It may be torn, not round, very big or does not change size in the light.
- Your eye looks cloudy.
- You have had an eye infection in the past month.
- You have glaucoma (high pressure inside your eye).
- You have "dry eye syndrome".
- You have injured your eye.
- You think there may be something in your eye or you have splashed something in your eye.
- You are already using other eye drops or ointment.
- You have had eye surgery or laser treatment in the last 6 months.

If you wear contact lenses, seek advice either from your contact lens practitioner (optician, optometrist) 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 the eye ointment.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, especially:
- Other eye ointments or eye drops
- Medicines which may affect your bone marrow.

Pregnancy and breast-feeding
Do not use this medicine if you are pregnant, breast-feeding or trying to become pregnant. If you become pregnant while using this ointment, stop using it and see your doctor.

Important information about some of the ingredients of this medicine
The ointment contains wool fat. This may cause a skin reaction around the eyes such as "contact dermatitis".

Driving and using machinery
The ointment may cause blurred vision due to stinging or stinging.
- This will only happen for a short period after it is put in your eye.
- If this happens do not drive or use machinery until you can see clearly.
3. How to use your medicine
Chloramphenicol eye ointment is used by placing a small amount (about 1cm) in the space between the lower eyelid and the eye. Always follow your pharmacist's instructions.
- Do not take it by mouth.
- Do not use for children under 2 years of age.
Adults and children aged 2 years and over:
A course of treatment lasts 5 days.
- If the eye ointment is being used alone, squeeze a thin line of ointment inside the lower eyelid of each affected eye 3 to 4 times a day. This means that you should use it about every 4 - 6 hours.
- If you are using chloramphenicol eye drops during the day and the eye ointment at night - apply the ointment at night, before going to bed.
Your pharmacist will advise which is the most suitable treatment for you.
When using the ointment
- Wash your hands before and after using the ointment.
- Sit or stand in front of a mirror.
- Tilt the tube cap.
- Gently pull lower eyelid down.
- Gently squeezing the tube, put about 1cm of ointment into the space between the lower eyelid and the eye.
- Let go of the eyelid and blink a few times. This will help spread the ointment over the eye.
- Try not to touch the eye, eyelashes, or anything else with the tip of the tube.
- Repeat for the other eye, if affected.
- Replace cap securely after use.
It is important to complete the course of treatment even if your eyes feel better.

Talk to your doctor immediately if:
- Your eyes get worse at any time.
- There is no improvement within 2 days.

Do not repeat the course of treatment without consulting your doctor or pharmacist.
If you miss a dose, use the ointment as directed above and then continue your normal course of treatment.
Do not share your eye ointment with anyone else.
If the contents of this tube are swallowed, contact your doctor straight away or go to your nearest hospital casualty department. Take with you the tube and container so that the medicine can be identified.

4. Possible side effects
Most people use chloramphenicol eye ointment without any problems, but it can have side effects, like all medicines.
Side effects that may occur include:
Reactions on or around the eye which are mild:
- stinging or burning
- irritation or itching
- inflammation of the skin (dermatitis).
The following side effects are very rare:
- affect less than 1 person in 10,000;
Blood disorders including:
- severe reduction in red blood cells (also called aplastic anaemia), which may cause weakness or breathlessness
- lower than normal blood cell counts (bone marrow depression) which may cause fever, joint pain or repeated infections.
- Grey baby syndrome in newborns and infants:
- low blood pressure
- vomiting
- blue colouring of the lips and pale "grey" skin.

If you have any of these symptoms, or have any other unusual symptoms or concerns with your medicine, stop using it and see your doctor or pharmacist straight away.

5. Storing your medicine
- Keep all medicines out of the reach and sight of children.
- Keep until prescribed.
- Do not store above 25°C.
- Do not use it after the expiry date shown on the tube and carton.
- Discard any unused eye ointment after completing your 6 day course of treatment or return it to your pharmacist.

6. Further Information
The name of your medicine is Chloramphenicol 1% w/w Antibiotic Eye Ointment.
This medicine contains the active ingredient Chloramphenicol 1% w/w.
Other ingredients are Liquid Paraffin, Wool Fat and Yellow Soft Paraffin.
Each tube contains 4 grams of smooth yellow eye ointment.
MA Holder: Calibehr Healthcare Ltd., South Yorkshire, S76 3GP.
Manufacturer: Martindale Pharmaceuticals, Bampton Road, Remsford, HM3 8UG, England.
Date approved: MM/YYYY

IF YOU WOULD LIKE A LEAFLET WITH LARGER PRINT PLEASE CALL 01226 779911

18
PIL for Goldeneye Chloramphenicol 1% w/w antibiotic eye ointment

GoldenEye
Chloramphenicol 1% w/w
Antibiotic Eye Ointment

Patient information leaflet

Read all the leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms get worse or do not improve.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

1. What your medicine is and what it is used for

Chloramphenicol belongs to a group of medicines called antibiotics. Antibiotics are used to infections caused by bacteria. Chloramphenicol eye ointment is for simple eye infections called “acute bacterial conjunctivitis.” This is sometimes known as “red eye” because the white part of the affected eye(s) will be red and/or the eyelids will be red or swollen. There may also be a sticky discharge which can make the eye difficult to open in the morning, and the eye may feel “gritty” or “irritated.”

2. Before you use your medicine

Do not use the ointment and talk to your doctor or pharmacist if:
- You are allergic to chloramphenicol or anything else in the ointment. Everything in the ointment is listed in Section 6 “Further information.”
- You or a member of your family has had problems with their blood or bone marrow. These problems can include a severe reduction in red blood cells or lower than normal blood count.
- The person needing to use the ointment is under 2 years of age.

3. Possible side effects

- Your eye is painful (rather than just feeling sore or gritty) if you have pain or swelling around the eye or face.
- Your sight is affected by loss of vision, reduced or blurred vision or you see halos around lights.
- It is too painful to open your eyes properly.
- Your pupil (the black circle in the centre of your eye) looks different. It may be torn, not round, vary big or does not change size in the light.
- Your eye looks cloudy.
- You have had an eye infection in the past month.
- You have glaucoma (high pressure inside your eye).
- You have “dry eye syndrome”.
- You have injured your eye.
- You think there may be something in your eye or you have splashed something in your eye.
- You are already using other eye drops or eye ointment.
- You have had eye surgery or laser treatment in the last 6 months.

If you use contact lenses, seek advice either from your contact lens practitioner (optician, optometrist) 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 the eye ointment.

Important information about some of the ingredients of this medicine
This ointment contains wool fat. This may cause a skin reaction around the eyes such as “contact dermatitis.”

4. Storing your medicine

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, especially:
Other eye ointments or eye drops.
Medicines which may affect your bone marrow.

5. Further information

Pregnancy and breast-feeding
Do not use this medicine if you are pregnant, breast-feeding or trying to become pregnant. If you become pregnant while using this ointment, stop using it and ask your doctor.

Driving and using machinery
The ointment may cause blurred vision due to smearing or stinging.
- This will only happen for a short period after it is put in your eye.
- If this happens do not drive or use machinery until you can see clearly.

6. Further information

UKPAR Chloramphenicol 1% w/w antibiotic eye ointment
PL 16028/0133-4
3. How to use your medicine

Chloramphenicol eye ointment is used by placing a small amount (about 1 cm) in the space between the lower eyelid and the eye. Always follow your pharmacist’s instructions:

• Do not take it by mouth.
• Do not use for children under 2 years of age.

Adults and children aged 2 years and over:

A course of treatment lasts 5 days:

• If the eye ointment is being used alone, squeeze a thin line of ointment inside the lower eyelid of each affected eye 3 to 4 times a day. This means that you should use it about every 4 - 6 hours.

• If you are using chloramphenicol eye drops during the day and the eye ointment at night - apply the ointment at night, before going to bed.

Your pharmacist will advise which is the most suitable treatment for you.

When using the ointment:

• Wash your hands before and after using the ointment.
• Sit or stand in front of a mirror.
• Take off the tube cap.
• Tilt head gently backwards.
• Gently pull lower eyelid down.
• Gently squeezing the tube, put about 10 cm of ointment into the space between the lower eyelid and the eye.
• Let go of the eyelid and blink a few times. This will help spread the ointment over the eye.
• Try not to touch the eye, eyelashes, or anything else with the tip of the tube.
• Repeat for the other eye, if affected.
• Replace cap securely after use.

It is important to complete the course of treatment even if your eyes feel better.

4. Possible side effects

Most people use chloramphenicol eye ointment without any problems, but it can have side effects, like all medicines.

Side effects that may occur include:

• Irritation or burning
• Itching or redness
• Inflammation of the skin (dermatitis).

The following side effects are very rare (effect less than 1 person in 10,000):

Blood disorders including:

• Decrease in red blood cells (also called aplastic anaemia), which may cause weakness or breathlessness.
• Decrease in bone marrow cells (bone marrow depression) which may cause fever, joint pain or bone pain.

Gray baby syndrome in newborns and infants:

• Low blood pressure
• Vomiting
• Blue colouring of the lips and palms of the skin.

If you have any of these symptoms, or have any other unusual symptoms or concerns with your medicine, stop using it and see your doctor or pharmacist straight away.

5. Storing your medicine

• Keep all medicines out of the reach and sight of children.
• Store at room temperature.
• Do not store above 25°C.
• Do not use after the expiry date shown on the tube and cap.
• Discard any unused eye ointment after completing your 5 day course of treatment or return it to your pharmacist.

6. Further Information

The name of your medicine is Goldeneye Chloramphenicol 1% w/w Antibiotic Eye Ointment.

This medicine contains the active ingredient Chloramphenicol 1% w/w.

Other ingredients are Liquid Paraffin, Wool Fat and Yellow Soft Paraffin. Each tube contains 4 grams of smooth yellow eye ointment.

MAA Holder: Gapharm Healthcare Ltd.,
South Yorkshire, S70 8GP.
Manufacturer: Martinco Pharmaceutical,
Bampton Road, Romford, RM8 8UG, England.
Date approved: MMM/YYYY

IF YOU WOULD LIKE A LEAFLET WITH LARGER PRINT PLEASE CALL 01226 779911
UKPAR Chloramphenicol 1% w/w antibiotic eye ointment

PL 16028/0133-4

LABELLING

PL 16028/0133 - Galpharm

Carton

Braille reads:
chloramphenicol
eye ointment
UKPAR Chloramphenicol 1% w/w antibiotic eye ointment

Tube label

**Chloramphenicol 1% w/w**

**Antibiotic Eye Ointment**

*For acute bacterial conjunctivitis*

Please read the leaflet before use.

For ocular use.

**FOR EXTERNAL USE ONLY** Sterile until opened.

For adults and children aged 2 years and over: Apply about 1 cm of ointment to the affected eye(s) 3 to 4 times daily.

For full dosage instructions: See leaflet.

Seek medical advice if symptoms get worse.

Discard after a 5 day course of treatment.

Contains wool fat.    PL 16028/0133

MA Holder: Galpharm Healthcare Ltd  P
Please read the enclosed leaflet before use.

FOR EXTERNAL USE ONLY.

For ear use. Sterile until opened.

For adults and

children aged 2

years and over:

A course of treatment lasts 5 days:

- If you are using just
  the eye ointment
  apply about 1 cm of
  ointment to the
  affected eye(s) 3 to 4
  times a day.
- If you are using
  chloramphenicol eye
  drops during the day
  and the eye ointment
  at night - apply the
  ointment at night.

Talk to your doctor
straight away if:

- Your eyes get worse
  at any time.
- There is no
  improvement within
  2 days.
- Discard after a 3 day
  course of treatment.

Do not use if

alcoholic:

- Chloramphenicol
  - the other
  ingredients.

Chloramphenicol 1.0% w/w
antibiotic eye
ointment

For acute bacterial conjunctivitis.
Chloramphenicol 1.0% w/w antibiotic eye ointment
For acute bacterial conjunctivitis
FOR EXTERNAL USE ONLY
Sterile until opened.
Please read the leaflet before use.
For ocular use.
For adults and children aged 2 years and over:
Apply about 1 cm of ointment to the affected eye(s)
3 to 4 times daily.
For full dosage instructions: See leaflet.
Seek medical advice if symptoms get worse.
Discard after a 5 day course of treatment.
Contains wool fat.
MA Holder: Galpharm Healthcare Ltd
PL 16028/0133
Chloramphenicol 1% w/w Antibiotic Eye Ointment

For acute bacterial conjunctivitis
Chloramphenicol 1% w/w
Antibiotic Eye Ointment

For acute bacterial conjunctivitis 4g

For external use only. Sterile until opened.

For ocular use.
Please read the leaflet before use.
For adults and children aged 2 years and over:
Apply about 1 cm of ointment to the affected eye(s) 3 to 4 times daily.
For full dosage instructions: See leaflet
Seek medical advice if symptoms get worse.
Discard after a 5 day course of treatment.
Contains wool fat. PL 16028/0133

MA Holder: Galpharm Healthcare Ltd
Tesco

Carton

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Braille reads:
chloramphenicol
eye ointment
Typharm
Carton

Do not store above 25°C.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Contains: Chloramphenicol 1% w/w as the active ingredient. Liquid Paraffin,
Methyl and Yellow Soft Paraffin (see leaflet for further information).

Do not use if allergic to: • Chloramphenicol • the other ingredients.

For external use only. Sterile until opened.

Manufactured by: Gubham Healthcare Ltd. South Yorkshire. S75 3RP.
Distributed by: Typharm Limited, 14D Windover Road, Rackheath, Norwich, NR13 6UJ, UK.

FOR ACUTE BACTERIAL CONJUNCTIVITIS

4g

PLEASE READ THE ENCLOSED LEAFLET BEFORE USE.

For adults and children aged 2 years and over: A course of treatment lasts 5 days:
• If you are using just the eye ointment, apply about 1 cm of ointment to the
affected eye(s) 3 to 4 times a day.
• If you are using chloramphenicol eye drops during the day and the eye
ointment at night, apply the ointment at night before going to bed.

Talk to your doctor straight away if:
• Your eyes get worse at any time.
• There is no improvement within 2 days. Discard after a 5 day course of treatment.

BN & EXP:

GoldenEye
Chloramphenicol 1% w/w Antibiotic Eye Ointment

FOR ACUTE BACTERIAL CONJUNCTIVITIS

4g
Braille reads:
chloramphenicol eye ointment
CHLORAMPHENICOL 1% w/w ANTIBIOTIC EYE OINTMENT 4g

FOR ACUTE BACTERIAL CONJUNCTIVITIS

FOR EXTERNAL USE ONLY
Sterile until opened.

For ocular use.
Please read the leaflet before use.
For adults and children aged 2 years and over:
Apply about 1 cm of ointment to the affected eye(s)
3 to 4 times daily.
For full dosage instructions: See leaflet
Seek medical advice if symptoms get worse.
Discard after a 5 day course of treatment.
Contains wool fat.

MA Holder: Galpharm Healthcare Ltd

PL 16028/0133
chloramphenicol eye ointment
Antibiotic Eye Ointment

For acute bacterial conjunctivitis

Please read the leaflet before use.

For ocular use.

For external use only. Sterile until opened.

For adults and children aged 2 years and over: Apply about 1 cm of ointment to the affected eye(s) 3 to 4 times daily.

For full dosage instructions: See leaflet.

Seek medical advice if symptoms get worse.

Discard after a 5 day course of treatment.

Contains wool fat.

MA Holder: Galpharm Healthcare Ltd