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CHLORAMPHENICOL 0.5% W/V ANTIBIOTIC EYE DROPS  
(CHLORAMPHENICOL)  

PL 16028/0131-2

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Galpharm Healthcare Limited Marketing Authorisations (licences) for the medicinal product Chloramphenicol 0.5% w/v antibiotic eye drops (PL 16028/0131-2) 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 drops are 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 0.5% w/v antibiotic eye drops (PL 00156/0109), authorised to Martindale Pharmaceuticals Limited on 3rd June 2005.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using Chloramphenicol 0.5% w/v antibiotic eye drops outweigh the risk; hence Marketing Authorisations have been granted.
CHLORAMPHENICOL 0.5% W/V ANTIBIOTIC EYE DROPS
(CHLORAMPHENICOL)

PL 16028/0131-2

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 0.5% w/v antibiotic eye drops (PL 16028/0131-2) 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 0.5% w/v antibiotic eye drops (PL 00156/0109) authorised to Martindale Pharmaceuticals Limited on 3rd June 2005.

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 16028/0131-2
PROPRIETARY NAME: Chloramphenicol 0.5% w/v antibiotic eye drops
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 0.5% w/v antibiotic eye drops. The proposed MA holder is ‘Galpharm Healthcare Limited’.

The reference product is Chloramphenicol 0.5% w/v antibiotic eye drops (PL 00156/0109), 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 0.5% w/v antibiotic eye drops. The products have been named in line with current requirements.

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

Chloramphenicol 0.5% w/v antibiotic eye drops are a clear, colourless to slightly yellow solution for ocular use. The eye drops contain Chloramphenicol 0.5% w/v (5 mg/ml). The eye drops are licensed for marketing in low density polyethylene bottle with dropper insert and high density polyethylene cap. There is a tamper evident seal, which is broken when the bottle is first opened. The fill volume is 10ml. Each bottle is packed into a carton with a patient information leaflet.

The approved shelf-life (24 months unopened, 28 days opened) and storage conditions (‘Store upright at 2 to 8°C in a dry place away from strong sunlight and do not freeze (for example keep in a fridge).’) 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 (clear, colourless to slightly yellow solution) 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 00156/0109, 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 0.5% w/v antibiotic eye drops (PL 00156/0109, 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.

A 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 testing shows that patients/users are able to act upon the information that the leaflet contains.

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 0.5% W/V ANTIBIOTIC EYE DROPS
(CHLORAMPHENICOL)

PL 16028/0131-2

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 0.5% W/V ANTIBIOTIC EYE DROPS
(CHLORAMPHENICOL)

PL 16028/0131-2

STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS
The UK Summary of Product Characteristics (SmPC) for Chloramphenicol 0.5% w/v antibiotic eye drops (PL 16028/0131 & 0132) is as follows. The only difference is the PL number:

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Chloramphenicol 0.5% w/v (5 mg/ml)
Excipient(s): Also contains Phenylmercuric nitrate.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Eye Drops, solution
Clear colourless to slightly yellow solution

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Treatment of acute bacterial conjunctivitis.

4.2 Posology and method of administration
Administration: For ocular use.
Adults (including the elderly) and children aged 2 years and over:
• Put one drop into the affected eye(s) every 2 hours for the first 48 hours and 4 hourly thereafter.
• To be used during waking hours only
• The course of treatment should be 5 days.

4.3 Contraindications
Hypersensitivity to chloramphenicol or to any other component of the preparation.
Family or personal history of blood dyscrasias including aplastic anaemia.

4.4 Special warnings and precautions for use
The eye drops should not be used in children under the age of 2, since there have been rare reports of leukemias and grey baby syndrome.
Prolonged use of chloramphenicol eye drops is not advisable. Chloramphenicol eye drops should not be used for more than 5 days at a time except on the advice of a doctor.
The label will state:
• Seek further immediate medical advice any time if symptoms worsen.
• Consult your doctor if your eye infection does not start to improve within 48 hours.
• Discard the medicine after a 5 day course of treatment.
• Do not use if you are allergic to chloramphenicol or any of the ingredients
Chloramphenicol eye drops 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 drops or eye ointment
- The patient has had eye surgery or laser treatment in the last 6 months
- Contact lens users

If this product is used following advice from a contact lens practitioner or doctor, contact lenses should not be worn during the period of treatment. Contact lens users may use glasses during treatment with chloramphenicol eye drops. Hard contact lens users and disposable contact lens users can start using their lenses again after successfully completing a course of treatment. Soft contact lens wearers should wait 24 hours after completing a course of treatment before starting to use their lenses again.

Information relating specifically to excipients in this formulation.

Phenylmercuric nitrate is irritant to the skin. Topical application to eyes has been associated with mercurialenitis and atypical band keratopathy.

4.5 Interaction with other medicinal products and other forms of interaction

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

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 drops. Chloramphenicol does cross the placenta and enter breast milk. Therefore chloramphenicol eye drops should not be used during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

The use of the eye drops may cause transient blurring of vision. Patients 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.
Sometimes the eye drops can be tasted or affect taste as they drain from the eye into the back of the mouth.

The prolonged use of eye drops containing a phenylmercuric preservative has been associated with skin irritation, primary atypical band keratopathy (changes to the cornea) and mercurial lentis (pigmentation of the anterior capsule of the lens).

Systemic effects:
Rarely cases of adverse haematological 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 drops.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
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
- Borax
- Boric Acid
- Phenylmercuric Nitrate
- Purified Water
6.2  Incompatibilities
None known

6.3  Shelf life
24 months Unopened
Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.

6.4  Special precautions for storage
Store upright at 2 to 8°C in a dry place away from strong sunlight and do not freeze (for example keep in a fridge).

6.5  Nature and contents of container
Low density polyethylene bottle and dropper insert with high density polyethylene cap. There is a tamper evident seal, which is broken when the bottle is first opened.
Fill volume is 10ml. Each bottle is then packed into a carton with a patient information leaflet.

6.6  Special precautions for disposal
No special requirements
No Data Held

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

8  MARKETING AUTHORISATION NUMBER(S)
PL 16028/0131
PL 16028/0132

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

10  DATE OF REVISION OF THE TEXT
05/11/2009
Chloramphenicol 0.5% w/v Antibiotic Eye Drops

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 drops are 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 eye drops and talk to your doctor or pharmacist if:
   - You are allergic to chloramphenicol or anything else in the eye drops. Everything in the eye drops 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 eye drops is under 2 years of age.

   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 drops.

   **Taking other medicines**

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

   **Pregnancy and breast-feeding**

   Do not use this medicine if you are pregnant. If you become pregnant while using chloramphenicol eye drops, stop using and see your doctor.

   **Important information about some of the ingredients of this medicine**

   This medicine contains Phenylmercuric Nitrate which may cause allergic reactions.

   **Driving and using machinery**

   The eye drops 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.

Do not use the eye drops 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 lots 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 eye ointment.
- You have had eye surgery or laser treatment in the last 6 months.

**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

PRODUCT INFORMATION LEAFLET
3. How to use your medicine

Chloramphenicol eye drops are used by placing in the space between the lower eyelid and the eye, for the treatment of acute bacterial conjunctivitis. 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, and the elderly:
A course of treatment lasts 5 days, to be used during waking hours only:
- One drop should be applied every 2 hours for the first 48 hours and thereafter every 4 hours.

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

When using the eye drops:
- Wash your hands before and after using the eye drops.
- Sit or stand in front of a mirror.
- Take off the bottle cap.
- Tilt head gently backwards.
- Gently pull lower eyelid down.
- Gently squeeze the dropper and put one drop 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 eye drops over the eye.
- Try not to touch the eye, eyelashes, or anything else with the tip of the dropper.
- Replace 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 eye drops as directed above and then continue your normal course of treatment.

Do not share your eye drops with anyone else.

If the contents of this bottle are swallowed, contact your doctor straight away or go to your nearest hospital casualty department. Take with you the bottle and container so that the medicine can be identified.

4. Possible side effects

Most people use chloramphenicol eye drops 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
  - Infammation 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 or pallor 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.
- Store until opened.
- Store upright between 2°C and 8°C in a dry, dark place (e.g. fridge).
- Do not freeze.
- Do not use after the expiry date shown on the bottle and carton.

Discard any unused eye drops after completing your 5-day course of treatment or return it to your pharmacist.

6. Further Information

The name of your medicine is:
Chloramphenicol 0.5% w/v Antibiotic Eye Drops. This medicine contains the active ingredient Chloramphenicol 0.5% w/v (8mg/ml).
Other ingredients are sodium chloride, glycine, sodium nitrate 0.005%, w/v and purified water. Each bottle contains 10ml of sterile liquid.

MA Holder: Galpharm Healthcare Ltd., South Yorkshire, S76 5SP.
Manufacturer: Martin’s Pharmaceuticals, Bampton Road, Rotherham, RIV 8UG, England.
Date approved: MM/YYYY

IF YOU WOULD LIKE A LEAFLET WITH LARGER PRINT PLEASE CALL 01226 779911
UKPAR Chloramphenicol 0.5% w/v antibiotic eye drops

LABELLING

PL 16028/0131

Galpharm

Carton
Braille

Braille reads:
chloramphenicol
eye drops

Blister strip

Read the enclosed leaflet carefully before use. Sterile until opened. For ocular use. Put 1 drop into the affected eye(s) every 2 hours for the first 48 hours, then every 4 hours thereafter. Use during waking hours only. The course of treatment should be 5 days. Seek further immediate medical advice any time if symptoms worsen. Consult your doctor if your eye infection does not start to improve within 48 hours. Discard the medicine after a 5 day course of treatment. Do not use if you are allergic to chloramphenicol or any of the ingredients. PL 16028/0131
UKPAR Chloramphenicol 0.5% w/v antibiotic eye drops

PL 16028/0131-2

Lloyds

Carton
UKPAR Chloramphenicol 0.5% w/v antibiotic eye drops

Braille reads:
chloramphenicol eye drops

See leaflet for instructions. For ocular use. Sterile until opened. Put 1 drop into the affected eye(s) every 2 hours for the first 48 hours, then every 4 hours thereafter. Use during waking hours only. The course of treatment should be 5 days. Seek further immediate medical advice any time if symptoms worsen. Consult your doctor if your eye infection does not start to improve within 48 hours. Discard the medicine after a 5 day course of treatment. Do not use if you are allergic to chloramphenicol or any of the ingredients.

Lloyds pharmacy
Chloramphenicol 0.5% w/v antibiotic eye drops
For acute bacterial conjunctivitis

PL 16028/0131-2

22
See leaflet for instructions. For ocular use. Sterile until opened. Put 1 drop into the affected eye(s) every 2 hours for the first 48 hours, then every 4 hours thereafter. Use during waking hours only. The course of treatment should be 5 days. Seek further immediate medical advice any time if symptoms worsen. Consult your doctor if your eye infection does not start to improve within 48 hours. Discard the medicine after a 5 day course of treatment. Do not use if you are allergic to chloramphenicol or any of the ingredients.
UKPAR Chloramphenicol 0.5% w/v antibiotic eye drops

Tesco

Read the enclosed leaflet carefully before use.

For ocular use

For adults and children aged 2 years and over: Put 1 drop into the affected eye(s) every 2 hours for the first 48 hours, then every 4 hours thereafter.

To be used during waking hours only. The course of treatment should be 5 days. Seek further immediate medical advice any time if symptoms worsen.

Consult your doctor if your eye infection does not start to improve within 48 hours. Discard the medicine after a 5 day course of treatment.

Do not use if you are allergic to chloramphenicol or any of the ingredients.

Children under 2 years:
Do not use

For external use only

Keep out of the reach and sight of children
Sterile until opened.
Store upright between 2°C and 8°C in a dry, dark place (e.g. fridge). Do not freeze.
Contains: Chloramphenicol 0.5% w/w, Phenylmercuric Nitrate 0.002% w/w, Borax, Bork Acid and Purified Water.

MA Holder: Qubihum Healthcare Ltd, South Yorkshire S75 2JP.
PL 16028/0131
Produced by the Marketing Authorisation Holder for Tesco Stores Ltd., Chester EN1 9SL, U.K.
SC106520
See leaflet for instructions. For ocular use. Sterile until opened. Put 1 drop into the affected eye(s) every 2 hours for the first 48 hours, then every 4 hours thereafter. Use during waking hours only. The course of treatment should be 5 days.

Seek further immediate medical advice any time if symptoms worsen. Consult your doctor if your eye infection does not start to improve within 48 hours. Discard the medicine after a 5 day course of treatment. Do not use if you are allergic to chloramphenicol or any of the ingredients.

PL 16028/0131
Braille reads:
chloramphenicol
eye drops

Blister strip