SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 0.5% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 0.5%w/v

Excipient(s) with known effect
Borax
Boric acid
Phenyl mercuric nitrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

A bright, colourless to yellow aqueous solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of bacterial conjunctivitis caused by the organisms *Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus*, Morax-Axenfeld and others in both adults and children over 2 years of age.

4.2 Posology and method of administration

Posology

Adults (and the elderly) and children over 2 years of age
The recommended dosage for adults (including the elderly) and children over the age of 2 is two drops to be applied to the affected eye every three hours. Treatment should be continued for at least 48 hours after the eye appears normal.

Should not be used in children under 2 years of age

Method of administration

For topical ocular use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the other excipients listed in section 6.1.
- Known personal or family history of blood dyscrasias including aplastic anaemia.
- Myelosuppression during previous exposure to chloramphenicol.
- Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future.

4.4 Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure. Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of the compound. Where chloramphenicol eye drops are used on a long-term or intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect any haemopoietic abnormalities.

In severe infections the topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate measures taken. Chloramphenicol should be reserved for use only in infections for which it is specifically indicated.

Chloramphenicol eye drops does not provide adequate coverage against Pseudomonas aeruginosa and Serratia marcescens.

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

Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time.

Patients should be referred to their doctor if any of the following apply:
• Disturbed vision
• Severe 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
• Contact lens use

Soft contact lenses should not be worn during treatment with chloramphenicol eye drops due to absorption of the preservative onto the lens which may cause damage to the lens. It is recommended that all types of contact lenses be avoided during ocular infections.

The packaging will convey the following information:
• 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

Phenylmercuric nitrate is irritating to the skin. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy. It may also cause allergic reactions.

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. Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established.

Chloramphenicol is known to penetrate well into foetal circulation and is found in breast milk at low concentrations. The reduced ability of the foetus and neonate to metabolise chloramphenicol may lead to the drug concentrating in the foetal or neonatal circulation. Therefore, this product is not recommended for use during pregnancy and lactation.

Topical ocular chloramphenicol must be used only if considered essential and not prophylactically or to treat minor infections.

4.7 Effects on ability to drive and use machines

The use of eye drops may cause transient blurring of vision. Patients should not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Eye Disorders:

Transient irritation, burning, stinging and sensitivity reactions such as itching and dermatitis.

Immune System Disorders:

Hypersensitivity reactions including angioedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis.

Blood and Lymphatic System Disorders:

Bone marrow depression and rarely aplastic anaemia has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected form the use of this compound.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Accidental ingestion of the drops is unlikely to cause systemic toxicity due to the low contents of the antibiotic in the product. If the irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If the symptoms persist after this, an ophthalmological examination should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibiotics, ATC code: S01AA01.

Chloramphenicol is a broad-spectrum antibiotic with bacteriostatic activity,

and is effective against a wide range of gram-negative and gram-positive organisms including Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus viridans, Moraxella species and Enterobacteriaceae, the main pathogens responsible for acute bacterial conjunctivitis. Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.

5.2 Pharmacokinetic properties

Not applicable to topical (ophthalmic) product

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which arc additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTIC ULARS

6.1 List of excipients

Borax

Boric acid

Phenyl mercuric nitrate

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from the date of manufacture.
28 days after first opening.

6.4 Special precautions for storage

Keep bottle in the outer carton, in order to protect from light. Store between 2°C and 8°C.

6.5 Nature and contents of container

A flexible polypropylene bottle, incorporating a polyethylene plug and cap assembly. The bottles contain 5ml or 10ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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Hettfordshire

WD18 9SS

Trading as: Co-pharma

8 MARKETING AUTHORISATION NUMBER(S)

PL 13606/0195

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/01/2012

10 DATE OF REVISION OF THE TEXT

05/03/2018