SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clorogen Eye Drops 0.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol Eye Drops BP 0.5% w/v contains 5mg/ml chloramphenicol.

Excipients with known effect

Borax and Boric acid (one ml of solution contains 3.075 mg boron)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye Drops, solution.

A bright, colourless to faint yellow aqueous solution

4.1 Therapeutic indications

Chloramphenicol is broad spectrum antibiotic indicated in both adults and children aged 2 years and over for the treatment of acute bacterial conjunctivitis.

4.2 Posology and method of administration

Posology

Adults, children aged 2 years and over and the elderly

One drop to be instilled into the infected eye every 2 hours for the first 48 hours and 4 hourly thereafter. To be used during waking hours only. The course of treatment is 5 days.

Treatment should continue for 5 days even if symptoms improve.

Method of Administration

For ocular use only.

4.3 Contraindications

Chloramphenicol eye drops must not be administered to patients who have:

- Hypersensitivity to chloramphenicol or to any other ingredient of the drops listed in section 6.1.
- Myelosuppression during previous exposure to chloramphenicol.
- Family history of blood dyscrasias.

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 by 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 the 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

Contact lenses should not be worn in an infected eye. Contact lenses should be removed during the period of treatment.

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

4.5 Interaction with other medicinal products and other forms of interaction

Bone marrow suppressant drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast-feeding

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

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur immediately after use and driving or using machinery should not occur until the vision is clear.

4.8 Undesirable effects

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. Treatment must be discontinued immediately in such cases.

Blood and lymphatic system disorders

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.

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 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

In view of the relatively small amount of chloramphenicol in Clorogen Eye Drops, overdosage with this product is unlikely to constitute a hazard. No specific treatment would be required.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmological 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.

Mechanism of action

Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis at an early stage.

Susceptibility

The following bacterial species are recognised conjunctival pathogens and may be susceptible to chloramphenicol. However due to the prevalence of acquired resistance to chloramphenicol in these species, the results of susceptibility testing should be taken into account if these are available. If no susceptibility test result is available, the choice of antibacterial agent should be influenced by local information on the likely prevalence of resistance to chloramphenicol in species that are commonly pathogenic in the eye.

Staphylococcus aureus

Streptococcus pyogenes

Streptococcus pneumoniae

Other beta-haemolytic streptococci

Haemophilius influenze

Moraxella catarrhalis

Neisseria gonorrhoeae

Resistance
Acquired resistance to chloramphenicol has been described in all the above species. Most commonly this is mediated by bacterial production of a chloramphenicol acetyl transferase that inactivates the drug. Chloramphenicol is not generally active against the enterobacteriaceae and is not active against non-fermenters such as Pseudomonas aeruginosa.

5.2 Pharmacokinetic properties

Following topical application to the eye, chloramphenicol may be absorbed into the aqueous humour. Sufficient chloramphenicol may be absorbed from the eye to appear in the systemic circulation.

Specific data on systemic absorption from this dosage presentation is not available.

Chloramphenicol is readily absorbed when given by mouth. Blood concentrations of 10µg per ml or more may be reached about 1 or 2 hours after a single dose of 1g by mouth, and blood concentrations of about 18.5µg per ml have been reported after multiple 1g doses. Choramphenicol palmitate is hydrolysed to chloramphenicol in the gastrointestinal tract prior to absorption, and the sodium succinate, which is given parenterally is probably hydrolysed to free drug mainly in the liver, lungs, and kidneys; such hydrolysis may be incomplete in infants and neonates, contributing to the variable pharmacokinetics in this age group. Chloramphenicol sodium succinate is, even in adults, only partially and variably hydrolysed, so that blood concentrations of chloramphenicol obtained after parenteral administration of the sodium succinate are often lower than those obtained after administration of chloramphenicol by mouth, with up to 30% of a dose excreted unchanged in the urine before hydrolysis can take place.

Chloramphenicol is widely distributed in body tissues and fluids; it enters the cerebrospinal fluid, 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 foetal circulation, into breast milk, and into the aqueous and vitreous humours 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 the urine but only 5 to 10% of an oral dose appears unchanged; the remainder is inactivated in the liver, mostly by conjugation with glucorinic acid. About 3% is excreted in the bile. However,

most is reabsorbed and only about 1%, mainly in the inactive form, is excreted in the faeces.

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 pharmacokinetics in a given patient.

5.3 Preclinical safety data

Nothing of relevance which is not included in other sections of the SPC

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Borax

Boric Acid

Water for injection

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

Unopened: 24 months

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 at 2ºC to 8ºC

Store in the original carton to protect from light.

6.5 Nature and contents of container

Pack Type A

10 ml Low density polyethylene bottle with polystyrene spiked cap.

Pack Type B

Low density polyethylene (LDPE)vial with insert-cap assembly, comprising of white coloured, HDPE screw-cap over a LDPE nozzle with tamper- evident LDPE dust-cover sealing the vial cap.

Pack size: 10 ml

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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