FRESHBORN CHLORAMPHENICOL EYE OINTMENT
(Chloramphenicol Eye Ointment BP 1%)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

FRESHBORN CHLORAMPHENICOL EYE OINTMENT

(Chloramphenicol Eye Ointment BP 1% w/w)

2. Qualitative and Quantitative Composition

Composition:

Chloramphenicol BP 1 % w/w

Ointment base q.s.

3. Pharmaceutical Form

Ophthalmic Ointment

4. Clinical Particulars

4.1 Therapeutic indications

Chloramphenicol is a broad-spectrum antibiotic for the treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfeld, Klebsiella/Enterobacter species and others.

Chloramphenicol is indicated in adults and children.

4.2 Posology and method of administration

Dosage and Administration

Posology

Adults, children and infants: The recommended dosage for adults, children and infants of all age groups is a small amount of the ointment to be applied to the affected eye every 3 hours or more frequently if required. Treatment should be continued for 48 hours after the eye appears normal.

Elderly: As for adults. Chloramphenicol has been used successfully at normal dosages in elderly patients. The pattern and incidence of adverse effects does not appear to differ from younger adults.

Paediatric population

Dosage adjustment may be necessary in newborn infants because of reduced systemic elimination due to immature metabolism and the risk of dose-related adverse effects. The maximum duration of treatment is 10-14 days.

Method of administration

Topical administration to the eye only.

4.3 Contraindications

The ointment must not be administered to:

Patients who have a history of hypersensitivity to chloramphenicol or to any of the excipients listed.

Patients who have experienced bone marrow suppression during previous exposure to chloramphenicol.

Patients with a known personal or family history of blood dyscrasias including aplastic anaemia.

4.4 Special warning and special precaution for use

Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported.

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.

If the eye ointment is to be 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 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. Chloramphenicol does not provide coverage against Pseudomonas spp. or serratia marcescens.

The use of topical chloramphenicol may occasionally result in overgrowth of nonsusceptible organisms including fungi. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate treatment given.

It is recommended that all types of contact lenses be avoided during ocular infections.

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;

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 using the eye ointment.

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.

4.5 Interaction with other medicinal products and form of interaction

None Known

If a concomitant topical treatment to the eye is required, the administration of the different products should be separated by an adequate period of time.

4.6 Pregnancy and lactation

The safety of topical chloramphenicol in pregnancy and lactation has not been established. Chloramphenicol may be absorbed systemically following the use of eye ointment and may cross the placenta and appear in breast milk. Therefore, this product is not recommended for use during pregnancy and lactation.

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 ophthalmic chloramphenicol. 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 suppression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognized to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

4.9 Overdose

Accidental overdose or accidental ingestion of the ointment is unlikely to cause systemic toxicity due to low content of chloramphenicol in the product.

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: S01AA01

Pharmacotherapeutic group: Antibiotics

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 recognized 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 as soon as 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.

Escherichia coli

Staphylococcus aureus

Streptococcus pyogenes

Streptococcus pneumoniae

Other beta-haemolytic streptococci

Haemophilius influenzae
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

Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye. Chloramphenicol may be absorbed systemically following the use of eye ointment.

5.3 Preclinical Studies

Pre-clinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

1. Hard paraffin BP
2. Cetostearyl alcohol BP
3. White Bees Wax BP
4. Polyethylene Glycol 6000
5. Propylene Glycol BP
6. White soft paraffin BP

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precaution for storage

Store at a temperature not exceeding 30°C. Protect from light.

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6.5 Nature contents of container

3.5 gm aluminum collapsible tube in a carton along with pack insert.

6.6 Instruction for use handling and disposal

Keep out of reach of children.

7. Manufacturer name

Alpa Laboratories Limited
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8. Marketing Authority

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