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

For excipients see 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

A bright, colourless to yellow aqueous solution

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.

4.2 Posology and method of administration

For topical ocular use

The recommended dosage for adults (including the elderly), children and infants of all age groups is two drops to be applied to the affected eye every three hours, or more frequently if required. Treatment should be continued for at least 48 hours after the eye appears normal.

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.

4.3 Contraindications

Should not be administered to patients hypersensitive to chloramphenicol, or any of the other ingredients of the preparation.

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

4.4 Special warnings and precautions for use

The association or chloramphenicol with childhood leukaemia's and Gray baby syndrome warrants careful consideration before using ocular chloramphenicol in neonates and small children.

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 is 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 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 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

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 drops.

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.

4.5 Interaction with other medicinal products and other forms of interaction

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. A serious side effect of chloramphenicol is Gray baby syndrome, known to occur if chloramphenicol is given to neonates.

Chloramphenicol has also been associated with childhood leukaemia's and bone marrow depression. It is likely that systemic absorption of chloramphenicol occurs following ocular administration.

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 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 an eye ointment may cause some 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.

Systemic effects:

Bone marrow depression, aplastic anaemia, angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation.

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.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals
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.

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 are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

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

Strides Pharma UK Ltd
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Hertfordshire
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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

27/04/2017