Summary of Product Characteristics

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Chloramphenicol Ophthalmic solution USP 0.5 % w/v

2. Qualitative and quantitative composition

Chloramphenicol USP…….0.5% w/v

Thiomersal USP …… 0.002% w/v

(As Preservative)

Aqueous buffered vehicle…..q.s.

3. Pharmaceutical form

Ophthalmic solution

4. Clinical particulars

4.1 Therapeutic indications

Chloramphenicol is a broad spectrum bacteriostatic antibiotic. It is active against a wide range of Gram-negative and Gram-positive organisms, including Salmonella typhi, Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae and Bacteroides fragilis. It has antirickettsial and antichlamydial activity. It is indicated for the topical treatment of superficial ocular infections caused by pathogens which are sensitive to it.

Chloramphenicol is indicated in adults and children.

4.2 Posology and method of administration

Adults (and the elderly) and children

One or two drops applied to each affected eye up to six times daily or more frequently if required. (Severe infections may require one to two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

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

For topical ocular use

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Myelosuprresssion during previous exposure to chloramphenicol.
- Known personal or family history of blood dyscrasias including aplastic anaemia

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 topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the 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 another 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.

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.

4.6 Pregnancy and lactation

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

Chloramphenicol may be absorbed systemically following the use of eye drops 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

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

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 from the use of this compound.

4.9 Overdose

Accidental ingestion of the drops is unlikely to cause systemic toxicity due to the low content of the antibiotic 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

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.

Pharmacotherapeutic group: Antibiotics

ATC Code: S01AA01

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 Toxicology

Oral, mouse: LD_{50} = 1500 mg/kg; Oral, rat: LD_{50} = 2500 mg/kg. Toxic reactions including fatalities have occurred in the premature and newborn; the signs and symptoms associated with these reactions have been referred to as the gray syndrome. Symptoms include (in order of appearance) abdominal distension with or without emesis, progressive pallid cyanosis, vasomotor collapse frequently accompanied by irregular respiration, and death within a few hours of onset of these symptoms.

6. Pharmaceutical particulars

6.1 List of excipients

Boric Acid

Borax

Glycerine

Polyethylene Glycol-400

Disodium edetate

Thiomersal

Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf life

36 months Unopened

1 month once opened

6.4 Special precautions

Screw the cap tightly to pierce the nozzle seal.

Use the solution within one month after first opening the container.

6.5 Warning:

1. If irritation persists or increases, discontinue the use and consult physician.
2. Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate the solution.

6.6 Nature and contents of container

Opaque White 10ml plastic vials with nozzle & 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.

7. Marketing authorisation holder

Clarion Medicals Ltd.

Jiangxi Xier Kangtai Pharmaceutical Co. Ltd.

Pin Code- 453446

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8. Marketing authorisation number(s)

To be allocated

9. Date of first authorisation/renewal of the authorisation

To be allocated

10. Date of revision of the text

To be allocated