

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF MEDICINAL PRODUCT

Chloromycetin 0.5% w/v Redidrops Eye Drops, Solution.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of the drops contains 5mg of chloramphenicol (0.5% w/v)

For a full list of excipients, see section 6.1 .

### 3. PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless, sterile, aqueous solution

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Chloramphenicol is a broad spectrum antibiotic for the treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms including: *Escherichia coli*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus haemolyticus*, *Morax-axenfeld*, *Klebsiella/Enterobacter* species and others.

#### 4.2 Posology and method of administration

Topical administration to the eye only.

##### Adults, children and infants:

The recommended dosage for adults, children and infants of all age groups is two drops to be applied to the affected eye every 3 hours or more frequently if required. Treatment should be continued for at least 48 hours after the eye appears normal.

##### Elderly(over 65 years):

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.

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### 4.3 Contra-indications

Chloromycetin Redidrops should not be administered to:

- Patients hypersensitive to chloramphenicol or any other component of the drops.
- Patients with a 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 Chloromycetin Redidrops 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.

Chloromycetin Redidrops 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

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- 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 medicaments and other forms of interaction**

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

### **4.6 Fertility, 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 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**

Blurring of vision can occur with the drops 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 Chloromycetin Redidrops. More serious side effects include bone marrow depression and rarely aplastic anaemia, angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation.

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### 4.9 Overdose

Accidental ingestion of Chloromycetin Redidrops 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.

### 5.2 Pharmacokinetic properties

Chloramphenicol is an extremely well established antibiotic and the successful use of the eye drops is well documented. Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.

### 5.3 Pre-clinical safety data

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

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Borax  
Boric acid  
Phenylmercuric nitrate  
Water for Injections

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

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2 years.

Discard remaining contents 28 days after opening.

### **6.4 Special precautions for storage**

Store between 2°C and 8°C. Keep container in the outer carton.

### **6.5 Nature and contents of container**

A flexible polypropylene bottle, incorporating a polyethylene plug and cap assembly containing 10ml of solution.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements

### **7. Marketing Authorisation Holder**

Goldshield Pharmaceuticals Limited  
NLA Tower,  
12-16 Addiscombe Road  
Croydon  
Surrey  
CRO OXT  
United Kingdom

### **8. Marketing authorisation number**

PA 899/28/2

### **9. Date of First Authorisation/ Renewal of Authorisation**

Date of first authorisation: 20 December 1974

Date of last renewal: 20 December 2009

### **10. Date of Revision of the text**

March 2011