

Product Summary

1. Trade Name of the Medicinal Product

Chloromycetin Redidrops

Chloramphenicol 0.5% w/v Eye Drops

2. **Qualitative and Quantitative Composition**

Each 1ml of the drops contains 5mg of chloramphenicol Ph Eur.

3. **Pharmaceutical Form**

Eye drops.

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.

4.3. Contra-indications

Chloromycetin Redidrops should not be administered to patients hypersensitive to chloramphenicol or any other component of the drops.

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. The prolonged use of antibiotics can cause sensitisation and occasionally result in overgrowth of non-susceptible organisms, including fungi. 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.

Soft contact lenses should not be worn during treatment with Chloromycetin Redidrops 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.

Chloromycetin Redidrops does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

4.5. Interactions with other Medicaments and other forms of Interaction

None known.

4.6. Pregnancy and Lactation

The safety of topical chloramphenicol in pregnancy and lactation has not been established. It should therefore only be used when considered essential by the physician.

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.

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.

Pharmacological Properties

5.1. Pharmacodynamic Properties

Chloramphenicol is a potent inhibitor of bacterial protein synthesis, and exerts its effects by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

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. Preclinical 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 and
Water for Injection

6.2. Incompatibilities

None known.

6.3 Shelf Life

24 Months

6.4. Special Precautions for Storage

Store between 2° C and 8° C. Discard remaining contents 28 days after opening.
Protect from light.

6.5. Nature and Contents of Container

A flexible polypropylene bottle incorporating a polyethylene plug and cap assembly.

Pack sizes: 5ml and 10ml.

6.6. Instruction for Use/Handling

None.

7. Marketing Authorisation Holder

Goldshield Pharmaceuticals,
NLA Tower,
12-16 Addiscombe Road
Croydon

CR0 OXT
UK

8. Marketing Authorisation Number

PL 12762/0206

9. Date of First Authorisation/Renewal of Authorisation

10 DATE OF REVISION OF THE TEXT

19/10/2009