Summary of Product Characteristics

1 NAME OF THE 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)

Excipient with known effect:
Phenylmercuric nitrate: 0.002 % w/v
Boric Acid: 1.5 % w/v
Borax: 0.4 % w/v

For the 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.

Chloramphenicol is indicated in both adults and children.

4.2 Posology and method of administration

Posology
Adults and children:

The recommended dosage for adults and children is two drops to be applied to the affected eye every 3 hours during waking 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.

Method of administration
Topical administration to the eye only.

Consideration should be given to national or local guidance on the appropriate use of antibacterial agents.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Chloromycetin Redidrops should not be administered to 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

Chloramphenicol should be used with caution in patients with a history of:

• 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.

Paediatric population

This medicine contains boron which has been shown to impair fertility in animals. While the potential for effect on fertility in humans is not known, it should be prescribed with particular caution to a child younger than 2 years, as the exposure to boron may exceed the established safety limit when used in line with the maximum recommended posology in this age group.

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 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

Chloramphenicol has a minor influence on the 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

Adverse reactions reported in clinical trials and in the post-marketing period are included in the table below. The frequencies correspond with:

System Organ Class	**Frequency**	**Adverse events**
Blood & lymphatic system disorders	Not known	Aplastic anaemia*, bone marrow failure*
Immune system disorders	Not known	Anaphylactic reaction*
Nervous system disorders	Not known	Burning sensation
Skin and subcutaneous tissue disorders	Not known	Angioedema*, dermatitis* (including vesicular & maculopapular dermatitis) urticaria
General disorders and administration site conditions	Not known	Pain (stinging sensation), pyrexia*

*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 HPRA Pharmacovigilance, Website: www.hpra.ie

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 occurs 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

Pharmacotherapeutic group: Antibiotic
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, including Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus

aureus, Streptococcus viridans, Moraxella species and Enterobacteriaceae, the main pathogens responsible for acute bacterial conjunctivitis.

Mechanism of action
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 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
Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
Discard remaining contents 28 days after opening.

6.4 Special precautions for storage

Store in a refrigerator between 2^{o}C and 8^{o}C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Amdipharm Limited
Temple Chambers
3 Burlington Road
Dublin 4
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1142/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 December 1974

Date of last renewal: 20 December 2009

10 DATE OF REVISION OF THE TEXT

August 2022