

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chloromycetin 1% w/w Ophthalmic Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of ointment contains 10 mg of chloramphenicol (1% w/w).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment

A smooth uniform translucent greasy ointment.

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 a small amount of the ointment 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.

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

Topical administration to the eye only.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with a known personal or family history of blood dyscrasias including aplastic anaemia should avoid use of this product.

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 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 haemopoietic abnormalities. Optic atrophy has been reported following a long term use of chloramphenicol.

In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Prolonged use of chloramphenicol 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 for infections for which it is specifically indicated. Chloramphenicol does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*. Contact lenses should be removed during the period of treatment.

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 ointment 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 ointment and patients should be warned not to drive or operate machinery unless 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:

Not known (cannot be estimated from the available data)

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Accidental ingestion of Chloromycetin 1% w/w Ophthalmic Ointment is unlikely to cause systemic toxicity due to the low content of the antibiotic. 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. 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

Liquid paraffin

Hydrophobic Base Gel (Sanobase 30W) *

* contains polyethylene dispersed in liquid paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 4 years
In use shelf life: Discard 28 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Supplied in a polyethylene tube laminated with aluminium and fitted with a white polyethylene nozzle and cap containing 4g of ointment.

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

Mercury Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER

PA0899/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

September 2016