

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloromytol 0.5% w/v Eye Drops

2. Qualitative and Quantitative Composition

Each 1ml of the drops contains 5mg of chloramphenicol

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.

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 Contraindications

Chloromytol 0.5% w/v Eye Drops 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, have 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 Chloromytol 0.5% w/v Eye Drops 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 may occasionally result in overgrowth of non-susceptible organisms, including fungi. If any new infection appears during the 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.

Soft contact lenses should not be worn during treatment with Chloromytol 0.5% w/v Eye Drops due to absorption of the preservative on to the lens which may cause damage to the lens. It is recommended that all types of contact lenses be avoided during ocular infections.

Chloramphenicol 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 the vision is clear.

4.8 Undesirable effects

Transient burning or stinging sensations may occur with the use of Chloromytol 0.5% w/v/ Eye Drops. 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 Chloromytol 0.5% w/v Eye 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.

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.

Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfeld, Klebsiella/Enterobacter species and others. Entobacteriaceae are variably resistant while Pseudomonas and Mycobacteria are usually resistant.

5.2 Pharmacokinetic Properties

Chloramphenicol is a 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 nitrated and
Water for Injection

6.2. Incompatibilities

None known.

6.3 Shelf life

Twenty four months

6.4. Special Precautions for Storage

Store between 2 and 8°C.
Keep container in the outer carton.
Discard remaining contents 28 days after opening.

6.5. Nature and Contents of Container

Flexible polypropylene bottles incorporating a polyethylene plug and cap assembly.

6.6. Instruction for Use/Handling

None

Administrative Data

7. Marketing Authorisation Holder

Goldshield Pharmaceuticals Ltd
NLA Tower
Croydon CR0 0XT
United Kingdom

8. Marketing Authorisation Number

PL 12762/0037

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

Date of first authorisation: 13 February 2001

Date of last renewal: 1 April 2009

10 DATE OF REVISION OF THE TEXT

15/07/2009