

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 1% w/w Eye Ointment
Golden Eye Antibiotic 1% w/w Eye Ointment
Optrex Bacterial conjunctivitis 1% w/w Eye ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over

4.2 Posology and method of administration

Topical administration to the eye only.

Adults, children aged 2 years and over and elderly

The recommended dose is a small amount of ointment (~ 1cm) to be applied to the affected eye(s). The ointment should be applied either at night if eye drops are used during the day, or 3 to 4 times a day if eye ointment is used alone

The pharmacist will advise on the most suitable treatment. Treatment should continue for 5 days even if symptoms improve.

4.3 Contraindications

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

- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.

- Patients with a family history of blood dyscrasias.

4.4 Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported (see section 4.8).

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.

The use of topical chloramphenicol may occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the patient should be referred to the doctor.

Prolonged or frequent intermittent topical application of chloramphenicol should be avoided since it may increase the likelihood of sensitisation and emergence of resistant organisms.

Do not use for more than 5 days without consulting your doctor.

The label will convey the following information:

- If you do not get better within 48 hours talk to a doctor.
- If your eyes get worse see a doctor straight away.
- Do not use this ointment if you are allergic to chloramphenicol or anything else in the ointment.
- After 5 days, throw away any ointment left.

For external use only

Keep all medicines out of the sight and reach of children.

Patients should be referred to a doctor if any of the following apply:

- Disturbed vision
- Any significant 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
- Dry eye syndrome
- Eye surgery or laser treatment in the last 6 months
- Eye injury
- Current use of other eye drops or eye ointment

If you wear contact lenses, seek advice either from your optometrist, contact lens practitioner 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 ointment.

4.5 Interaction with other medicinal products and other forms of interaction

Bone marrow depressant drugs.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. Therefore, use only when considered essential by the physician.

4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur immediately after use and *patients should be warned that* driving or using machinery should not occur until the vision is clear.

SUMMARY OF PRODUCT CHARACTERISTICS

4.8 Undesirable effects

Transient burning or stinging sensations may occur. 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.

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 the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Accidental ingestion of the eye ointment 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

ATC CODE(S): S01AA01. Sensory. Ophthalmologicals. Antiinfectives. Antibiotics.

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms.

5.2 Pharmacokinetic properties

Chloramphenicol enters the aqueous humour following topical application.

Chloramphenicol is widely distributed in body tissues and fluids: it enters the CSF, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the fetal circulation, into breast milk, and into the aqueous and vitreous humour of the eye. Up to about 60% in the circulation is bound to plasma protein. The half-life of chloramphenicol has been reported to range from 1.5 to 4 hours; the half-life is prolonged in patients with severe hepatic impairment and is also much longer in neonates. Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites.

Chloramphenicol is excreted mainly in urine.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetic in a given patient.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
White petroleum

6.2 Incompatibilities

None known

6.3 Shelf life

Contents are sterile until opened.

Unopened: 48 months

Opened: 28 days

Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

4g aluminium tube and polyethylene cap.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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09/12/2024

10 DATE OF REVISION OF THE TEXT

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