

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 1.0% w/w Antibiotic Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains Chloramphenicol 1.0% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye ointment

A yellowish-white ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over.

4.2 Posology and method of administration

Posology

Adults (including elderly people) and children aged 2 years and over:

If using just the eye ointment, apply about 1 cm of ointment to the affected eye(s) 3 to 4 times a day.

If using chloramphenicol eye drops during the day and the eye ointment at night - apply the ointment at night, before going to bed.

The course of treatment is 5 days.

Method of administration

For topical ocular use.

The ointment is applied into the space between the lower eyelid and the eye.

4.3 Contraindications

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

Patients who have experienced myelosuppression during previous exposure to chloramphenicol.

Family or personal 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 Chloramphenicol antibiotic eye ointment 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.

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 use of chloramphenicol eye drops is not advisable, 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*.

Chloramphenicol eye ointment should not be used for more than 5 days at a time except on the advice of 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.

The label will state:

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

- After 5 days, throw away any ointment left.

For external use only

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

Chloramphenicol eye ointment should not be recommended under the following circumstances (in these circumstances patients should be referred to their doctor):

- Severe pain within the eye
- Disturbed vision
- Photophobia
- Eye inflammation associated with a rash on the scalp or face
- The pupil looks unusual
- The eye looks cloudy
- 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:

- Associated pain or swelling around the eye or face
- The patient has had conjunctivitis previously in the recent past
- The patient has glaucoma
- The patient has dry eye syndrome
- The patient has an eye injury
- The patient is already using other eye ointments or eye drops
- The patient has had eye surgery or laser treatment in the last 6 months

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 the eye ointment.

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. Therefore, use only when considered essential by the physician.

Chloramphenicol may be absorbed systemically following the use of the eye ointment. Chloramphenicol does cross the placenta and enter breast milk. Therefore, chloramphenicol eye ointment should not be used during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation of the ointment. User should not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Transient burning or stinging sensations may occur with the use of Chloramphenicol Antibiotic Eye Ointment. 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 at: 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 Chloramphenicol Antibiotic Eye Ointment is unlikely to cause systemic toxicity due to the low content of the antibiotic. 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

Pharmacotherapeutic group ATC CODE(S): S01AA01. Sensory. Ophthalmologicals. Antiinfectives, antibiotics for topical use.

Chloramphenicol is a broad spectrum antibiotic which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis* (formerly known as *Branhamella catarrhalis*) particularly in children.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus*, and streptococci such as *Str. pneumoniae*, *Str. pyogenes*, and the viridans streptococci. Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

5.2 Pharmacokinetic properties

Evidence suggests that chloramphenicol is absorbed systemically via topical ocular administration. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, 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; it is also secreted in saliva, with the highest concentrations occurring in the kidneys and liver. Up to about 60% in the circulation is bound to plasma protein.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half-life of 1.5 to 4 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours in the latter.

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

No additional 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 soft paraffin

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and contents of container

Aluminium tube with epoxy-phenolic-ureic resin internal coating.

Polyethylene screw cap and nozzle.

Pack size 4g tube

6.6 Special precautions for disposal

Sterile until opened.

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

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.
Bampton Road, Harold Hill
Romford
Essex
RM3 8UG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00156/0363

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/05/2018

10 DATE OF REVISION OF THE TEXT

06/07/2023

