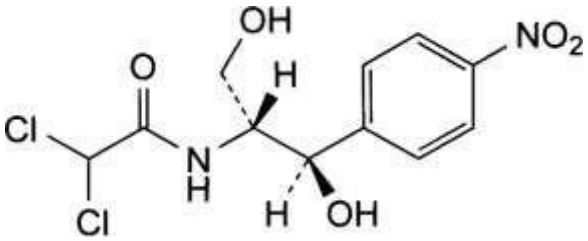
Product Information

MINIMS® CHLORAMPHENICOL 0.5% EYE DROPS

NAME OF THE MEDICINE

Chloramphenicol

Chemical structure:



Chemical name: 2,2-dichloro-N-[(α-R, β-R)-β-hydroxy-α-hydroxymethyl-4-nitrophenethylene]-acetamide

Molecular formula: $C_{11}H_{12}Cl_2N_2O_5$

Molecular weight: 323.1

CAS number: 56-75-7

DESCRIPTION

Chloramphenicol is a white to greyish-white or yellowish-white, fine crystal powder or fine crystals, needles or elongated plates.

Minims Chloramphenicol Eye Drops are single-use clear colourless sterile eye drops containing 0.5% chloramphenicol. The other ingredients are borax, boric acid and purified water. No preservatives are included in the formulation.

PHARMACOLOGY

Chloramphenicol is a broad-spectrum antibiotic, which is effective against both Gram-positive and Gram-negative organisms. Chloramphenicol is bacteriostatic and acts by inhibition of protein synthesis. Chloramphenicol is an antimicrobial substance produced by the growth of certain strains of *Streptomyces venezuelae*.

CLINICAL TRIALS

This information is not available.

INDICATIONS

For the treatment of bacterial conjunctivitis. For use under medical supervision only in the treatment of other superficial ocular infections caused by chloramphenicol-sensitive organisms.

CONTRAINDICATIONS

Chloramphenicol is contraindicated in individuals with a history of hypersensitivity to any excipients and / or toxic reaction to the drug.

PRECAUTIONS

This product should not be recommended for OTC use under the following circumstances:

- Photophobia
- Severe pain in the eye or pain and swelling around the eye
- Loss of, reduced or blurred vision
- Restriction of eye movement
- Cloudy cornea
- Copious yellow-green purulent discharge that accumulates after being wiped away
- Contact lens wearer
- Abnormal pupils
- Injury to the eye or suspicion of a foreign body in the eye
- History of welding without eye protection immediately prior to onset of symptoms
- Glaucoma
- Dry eye syndrome
- Patient is using other eye drops or eye ointments at the time of presentation
- Patient has had eye surgery or laser treatment in the past six months
- Individual or family history of bone marrow problems
- Recent overseas travel
- Patient has had similar symptoms in the past
- Patient feels unwell

In these cases, referral to a doctor or optometrist is required.

Instructions to Patients:

If symptoms worsen at any time or if the eye infection does not improve within 48 hours, seek prompt medical advice.

Patients who wear contact lenses should be advised to seek advice from their doctor or optometrist before using this product. Contact lenses should not be worn during the course of treatment with this product. If wearing **hard** or **disposable** contact lenses, patients can start using their lenses again after successfully completing the course of treatment. If wearing **soft** contact lenses, patients should wait 24 hours after successfully completing a course of treatment before starting to use their lenses again.

Local Effects:

Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis may occur.

Discontinue promptly if sensitisation or irritation occurs.

Systemic Effects:
The mechanism for irreversible asplastic anaemia following ophthalmic use of chloramphenicol has not been established.
Bone marrow hypoplasia, including aspastic anaemia and death has been rarely reported following local application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment.
Ophthalmic chloramphenicol may retard corneal wound healing.

Effects on ability to drive and use machines:
May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery unless vision is clear.

In severe infections topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

The use of this antibiotic, as with other antibiotics, may result in the overgrowth of non-susceptible organisms, including fungi. If infections caused by non-susceptible organism appear during therapy, its use should be discontinued and appropriate measures taken.

Use in Pregnancy (Category A)/ Use in Lactation:
Category A. Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Systematically absorbed / administered forms of chloramphenicol enter the foetal circulation and are distributed into breast milk. If given systematically to the mother shortly before parturition or whilst breastfeeding, chloramphenicol may cause bone marrow suppression of the neonate or the "grey baby syndrome", characterised by cyanosis and hypothermia, owing to the limited glucuronidating capacity of the neonate's liver. However, limited absorption following ophthalmic use at the recommended dosage is generally not expected to pose a risk to the foetus or neonate.

There are no studies on use in lactation.

INTERACTIONS WITH OTHER MEDICINES

Chymotrypsin (an eye drop used during cataract surgery) may not work properly if it is given at the same time as Minims Chloramphenicol.

ADVERSE EFFECTS

Blood dyscrasias have been reported in association with use of chloramphenicol (refer to Precautions).

Chloramphenicol is absorbed systemically from the eye, and toxicity has been reported following chronic exposure. Dose-related toxicity following a singular ocular exposure is unlikely.

Signs of local irritation with subjective symptoms of itching or burning. More serious side effects include angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are

causes for discontinuing the medication. Similar sensitivity reactions to other material in topical preparations may also occur.

DOSAGE AND ADMINISTRATION

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of drops. This blocks the passage of the drops via the naso-lacrimal duct to wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

Adults and children 2 years of age and over: one to two drops applied to each affected eye every two to six hours for two to three days. The interval between applications may then be increased. Severe infections may require one to two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled.

Treatment should be continued for at least 48 hours after the eye appears normal. Do not use for more than 5 days in total except on medical advice.

Each Minims unit should be discarded after a single dose.

The product is not recommended for children under 2 years of age except on medical advice.

OVERDOSAGE

Accidental ingestion of the drug is unlikely to cause any toxicity due to the low content of antibiotic. Minims Chloramphenicol contain borax and boric acid as a buffer and if ingestion by infants or young children occurs, the Poisons Information centre should be contacted on 13 11 26. It is advisable to keep medication out of the reach of children.

Treatment:
If irritation, pain, lacrimation or photophobia occurs after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmic examination should be considered.

PRESENTATION AND STORAGE CONDITIONS

Presentation: Minims Chloramphenicol Eye Drops are supplied as a clear colourless sterile eye drops in a single use polypropylene tube (unit) overwrapped in a polyester sachet. The sachets are packed in cartons of 20 units. Each unit containing approximately 0.5 mL solution.

Storage: Store at 2°C to 8°C. Refrigerate. Do not freeze. Do not expose to strong light.

POISONS SCHEDULE OF THE MEDICINE

Pharmacist Only Medicine: S3

NAME AND ADDRESS OF SPONSOR

Bausch & Lomb (Australia) Pty Ltd
Level 2, 12 Help Street
Chatswood, NSW 2067

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG)

30th October 1991

DATE OF MOST RECENT AMENDMENT

4th April 2018