

100x200 mm

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**For the use of Registered Medical Practitioner of Hospital or a Laboratory only**

Chloramphenicol Eye Drops BP  
**CHLOROMYCETIN**

**COMPOSITION:**

Chloramphenicol	BP	0.5% w/v
Phenylmercuric Nitrate	BP	0.001% w/v
(as Preservative)		
Sterile Isotonic base		q.s.

**CLINICAL PHARMACOLOGY**

Pharmacotherapeutic group: Ophthalmological antibiotic, ATC code: S01AA01  
Chloramphenicol is an antibiotic which is mainly bacteriostatic in action, but exerts a bactericidal effect against some strains of gram-positive cocci and against Haemophilus influenzae and Neisseria. It has a broad spectrum of action against both gram-positive and gram-negative bacteria, rickettsiae and chlamydia.

**Posology and Method of administration**

**Posology**

**Adults (including the elderly) and children**

One to two drops applied topically to each affected eye up to six times daily or more frequently if required. To decrease the risk for recurrent infection, treatment should continue for an additional 2 days after symptoms disappear. The maximum recommended treatment duration is 14 days.

**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.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute following instillation of the drops.

**Method of administration**

**For ocular use.**

Chloramphenicol eye drops solution is a sterile solution.

Patients should be instructed to wash their hands before use and avoid allowing the tip of the container to come into contact with the eye or surrounding structures as this could cause injury to the eye.

Patients should also be instructed that ocular solutions, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

**INDICATION AND USAGE**

Chloramphenicol is indicated in adults and children for the treatment of acute bacterial conjunctivitis.

Considerations should be given to official guidance on the appropriate use of antibacterial agents.

**CONTRA-INDICATION**

Hypersensitivity to the active substance.

**WARNINGS AND PRECAUTIONS**

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

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms.

Contact lenses should not be worn in an infected eye. Contact lenses should be removed during the period of treatment.

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

Patients with a history of contact hypersensitivity to silver should not use this product as dispensed drops may contain traces of silver.

**SIDE EFFECTS**

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

**OVERDOSE**

Accidental ingestion of the 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.  
In view of the relatively small amount of chloramphenicol in Chloramphenicol Eye Drops, overdosage with this product is unlikely to constitute a hazard. No specific treatment would be required.

**DOSAGE & MODE OF ADMINISTRATION**

**Adults (and the elderly) and children**

One or two drops applied to each affected eye up to six times daily or more frequently if required. (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).

**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:** For topical ocular use.

**STORAGE CONDITION**

Store in a cool & dry place. Protect from light.  
Do not freeze.

**MEDICINE : KEEP OUT OF REACH OF CHILDREN.**

**PRESENTATION**

10 ml LDPE vial packed in a unit carton along with leaflet.



SCOTT-EDIL

Manufactured by :

**Scott-Edil Pharmacia Ltd.**

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