1. Name of the medicinal product

CHLORAMPHENICOL EYE/EAR DROPS BP

0.5% W/V

2. Qualitative and quantitative composition

Chloramphenicol BP

..... % w/v Phenyl

Mercuric Nitrate BP .....%
w/v
(as preservative)
Sterile Aqueous Vehicle Q.S.
(for the full list of excipients, see section 6.1)

3. Pharmaceutical form

Solution.

Clear, colorless to light yellow color solution.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of acute bacterial conjunctivitis caused by the organisms E. coli, Haemophilus influenza, Staph Aureaus, Streptoccocus Heomolyticus, Morax Axenfield and others.

4.2 Posology and method of administration

For topical administration to the eye - The recommended period of treatment is 5 days. Adults and Children: The recommended dosage is for adults, and children aged 2 years and over. One drop to be applied to the infected eye every 3 hours for the first 48 hours and then every 4 hours thereafter. Treatment should be continued for 5 days unless otherwise as directed by the physician Elderly: As for adults. Chloramphenicol has been used successfully at recommended dosages in elderly patients.

4.3 Contraindications

Chloramphenicol eye drops should not be administered to:

- Patients hypersensitive to chloramphenicol or to any other component of the drops.
- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.

4.4 Patients with a known personal or family history of blood dyscrasias including aplastic anaemia.Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure.

In severe infection and where it is not confined to the conjunctivae, the patient should be referred to the doctor in case 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 treatment or symptoms worsen, the patient should consult a doctor immediately.

Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time. Chloramphenicol 0.5% w/v Eye Drops does not provide adequate coverage against Pseudomonas aeruginosa and Serratia marcescens.

Further precautions include

- If symptoms do not improve within 48 hours talk to your doctor
- Seek further immediate medical advice at any time if symptoms worsen
- Do not use if you are allergic to chloramphenicol or any of the ingredients
- Discard any remaining eye drops after the five-day course of treatment Patients should be referred to their doctor if any of the following apply:
- Disturbed vision
- Severe 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

• Contact lens use Contact lens wearers should only use Chloramphenicol 0.5% w/v eye drops on the advice of a doctor or contact lens practitioner. Contact lenses should not be worn during treatment. Soft contact lenses should not be worn until 24 hours after the course of treatment has finished. This medicine contains Phenylmercuric nitrate which is irritating to the skin. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy.

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 during 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

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

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 rare, it should be borne in mind when assessing the benefits expected from the use of the compound.

Transient burning or stinging sensations may occur with the use of Chloramphenicol 0.5% w/v Eye Drops. More serious side effects include hypersensitivity reactions that may present as angioneurotic oedema, urticaria, anaphylaxis, fever, and vesicular and maculopapular dermatitis. If this happens treatment must be discontinued immediately. The preservative, Phynylmercuric nitrate, may cause allergic reactions.

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 to the National Regulatory Authority.

4.9 Overdose

Accidental ingestion of Chloramphenicol 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 occurs 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

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of Gram-negative and Gram-positive organisms, including Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus viridans, Moraxella species and Enterobacteriaceae, the main pathogens responsible for acute bacterial conjunctivitis.

Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.

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 humor 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

Sr. No	Ingredients	Standard
1.	Phenyl Mercuric Nitrate	BP
2.	Boric Acid	BP
3.	Borax	BP

4.	Polysorbate-80 (Tween -80)	BP
5.	Propylene Glycol	BP
6.	Sterile aqueous vehicle	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened shelf-life is

36 months.

Opened shelf- 28 days

6.4 Special precautions for storage

Store below 30° C.

6.5 Nature and contents of container

5 ml Plastic bottle

6.6 Special precautions for disposal and other handling

No special requirement

7 Marketing Authorization Holder and

Manufacturing Site Address Marketing

Authorization Holder:

Name: Krishna Chemists Limited Address: Industrial area, Lusaka road, 3rd floor, Metrix hardware, PO Box:3328-00506, Nairobi-Kenya

Manufactured By

MERCURY LABORATORIES LIMITED

Address: 2/13 & 2/14, P.B. NO. 3001, BIDC, VADODARA, GUJARAT 390016.

8 Marketing Authorization Number

2646

9. Date of first Registration/ Renewal of the Registration

2025 July 17

10. Date of Revision of the Text

11/06/2025