

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Chloramphenicol 0.5% w/v eye drops solution
Vanmycetin eye drops

2. Qualitative and quantitative composition

Each mL of solution contains 5 mg of chloramphenicol. One drop (≈ 0.05 ml) contains 0.25 mg of chloramphenicol.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops solution.

A bright, colourless to faint-yellow aqueous solution, practically clear and free from particles.

4. Clinical particulars

4.1 Therapeutic indications

Chloramphenicol is a broad-spectrum antibiotic indicated in both adults and children for the treatment of bacterial conjunctivitis caused by chloramphenicol-susceptible organisms including *Escherichia coli*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus haemolyticus*, *Moraxella*, *Klebsiella*, *Enterobacter* species and others.

4.2 Posology and method of administration

Posology

Adults and children (including the Elderly)

The recommended dosage for adults and children is two drops to be applied to the affected eye every three hours or more frequently if required. Treatment should be continued for at least 48 hours after the eye appears normal.

Paediatric population

Dosage adjustment may be necessary for 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 ocular use only.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
- Myelosuppression during previous exposure to chloramphenicol.
- Known personal or family 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 eye drops are 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 any haemopoietic abnormalities.
- In severe infections, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment.
- Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms. If any new infection appears during the treatment, the antibiotic should be discontinued and appropriate measures taken.
- Chloramphenicol should be reserved for use only in infections for which it is specifically indicated.
- Chloramphenicol does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

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

- Disturbed vision
- Severe pain in 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.

Soft contact lenses should not be worn during treatment with chloramphenicol eye drops due to absorption of the preservative onto the lens which may cause damage to the lens. It is recommended that all types of contact lenses be avoided during ocular infections.

Excipients

This medicine contains **phenylmercuric nitrate**, which may cause allergic reactions.

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 Pregnancy, fertility and lactation

Chloramphenicol may be absorbed systemically following the use of eye drops and may cross the placenta and appear in breast milk. Therefore, this product is not recommended for use during pregnancy and lactation.

4.7 Effects on the ability to drive and use machines

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

4.8 Undesirable effects

Eye disorders

Transient irritation, burning, stinging and sensitivity reactions such as itching and dermatitis.

Immune System Disorders

Hypersensitivity reactions include angioedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis.

Blood and lymphatic system disorders

Bone marrow depression and rarely aplastic anaemia have 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 this compound.

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 Adverse Drug Reaction (ADR)/ Serious Adverse Event (SAE) electronic form linked to the MCAZ database using the following link: <https://primaryreporting.who-umc.org/ZW>.

4.9 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological classification: 19.1.1 Ophthalmic medicines: Antibiotics.

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 an extremely well-established antibiotic and the successful use of the eye drops is well documented. Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Borax

Boric acid

Phenylmercuric nitrate

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a refrigerator, 2-8 °C.

6.5 Nature and contents of the container

An LDPE vial with a spike high-impact polystyrene (hips) cap.

Fill volume: 10 ml.

Pack size: 1 vial per carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

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8. MANUFACTURER

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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/19.1.1/6433

Zimbabwe category for distribution: Prescription Preparations (P.P.)

10. DATE OF REVISION OF THE TEXT

March 2024