VANMYCETIN EYE DROPS

Chloramphenicol Eye Drops BP

PRESCRIBING INFORMATION (SUMMARY OF PRODUCT CHARACTERISTICS)

1. Name of the medicinal product

VANMYCETIN EYE DROPS (Chloramphenicol Eye Drops BP)

2. Qualitative and quantitative composition

Chloramphenicol Ph.Eur.....% w / v

Phenylmercuric Nitrate Ph.Eur.....% w/v

(As preservative)

Aqueous buffer vehicle.....q.s

3. Pharmaceutical form

Dosage Form: Eye Drops

Description: A bright colorless to faint yellow aqueous solution, practically clear and practically 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 eye appears normal.

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. Themaximum duration of treatment is 10-14 days.

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Administration: For ocular use only.

4.3.Contraindications

- Hypersensitivity to the active substance, chloramphenicol or to any of the excipients listed insection 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 reportedfollowing 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 mindwhen 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 beadvisable 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 Eye Drops does not provide adequate coverage against Pseudomonasaeruginosa and Serratia marcescens.

Do not use for more than 5 days without consulting a doctor.

Medical advice should be sought if there is no improvement in the condition after 2 days or ifsymptoms worsen at any time.

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 medicalhistory 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 dueto 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.

The packaging will convey the following information:

- 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

Phenylmercuric nitrate is irritating to the skin. Topical application to eyes has been associatedwith 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 bonemarrow function should be avoided.

4.6.Pregnancy and lactation

The safety of topical use of chloramphenicol in pregnancy and lactation has not been established.

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 ability to drive and use machines

Transient blurring of vision may occur immediately after use and driving or using machineryshould 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 including angioedema, anaphylaxis, urticaria, fever, vesicular andmaculopapular dermatitis.

Blood and lymphatic system disorders:

Bone marrow depression and rarely aplastic anaemia 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 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.

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.

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5. Pharmacological properties

5.1.Pharmacodynamic Properties

Pharmacotherapeutic group:

AntibioticsATC code: S01AA01

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 aqueoushumour following local application to the eye.

5.3.Preclinical safety data

Nothing of relevance which is not included in other sections of the SPC.

6. Pharmaceutical particulars

6.1.List of excipients

Borax Ph.Eur, Boric Acid Ph.Eur., Phenylmercuric Nitrate Ph.Eur., Water For InjectionPh.Eur.

6.2.Incompatibilities:

Not applicable

6.3.Shelf life:

24 months from Date of manufacture. Discard within 28 days of opening.

6.4.Special precautions for storage:

Store in a refrigerator (2ºC – 8 ºC). Protect from light

6.5.Nature and contents of container:

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10 mL labeled LDPE vial with HIPS cap packed in a carton along with package insert.

6.6. Special precautions for disposal and other handling Not Applicable

7. Marketing authorization holder:

FDC Limited,
142-48, Swami Vivekanand Road,
Jogesgwari (West),
Mumbai – 400102,
India.

8. Marketing authorization number(s): Product License **TAN 21 HM 0222**

9. Date of first authorization/renewal of the authorization:

03/06/2021

10. Date of revision of the text: Not Applicable