SUMMARY PRODUCT CHARACTERISTICS (SPC)

CHLORAMPHENICOL EYE DROPS (Ivyphenicol eye drops)

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1. NAME OF MEDICINAL PRODUCT:

CHLORAMPHENICOL EYE DROPS (Ivyphenicol eye drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition API:

Chloramphenicol BP

Quantitative composition: **Chloramphenicol 0.5%$^{w}/_{v}$. (5 mg/ml)**

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

EYE DROP
10ml, Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 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 only. 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.
• Patients with a known personal or family history of blood dyscrasias including aplastic anaemia.

4.4 Special warnings and pre cautions 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.
Ivyphenicol 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 Ivyphenicol 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 Interactions with other medicinal products and other forms of interactions
The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

4.6 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 Ivyphenicol 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.

4.9 Overdose

Accidental ingestion of Ivyphenicol 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 Pre-clinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of ingredient	**Reference**	**Amount per 10 ml**	**Function/Reason For inclusion.**
Boric acid	BP	150mg	Buffering agent
Borax	BP	25mg	Buffering agent
Phenyl mercuric nitrate	BP	0.2mg	Preservative
Water for injection	BP	Quantity Sufficient to volume	Solvent

6.2 Incompatibilities

Not applicable

6.3 Shelf life:

Unopened shelf-life is 24 months.

Opened shelf-life 28 days.

But the patient is advised to discard any remaining drops after the prescribed course of treatment.

6.4 Special precautions for storage:

Store in a cool place (below 25° C) away from light. Keep out of reach of children

6.5 Nature and contents of container:
10ml low density polyethylene bottles with a polypropylene spiked cap.

6.6 Special precautions for use and disposal:

No special requirement

7. MARKETING AUTHORISATION HOLDER

(Company) Name: **IVEE AQUA EPZ LTD.**

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8. MARKETING AUTHORISATION NUMBER

Registration number: **NAFDAC REG NO. 04 – 3366**

9. DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

10. DATE OF REVISION OF TEXT

November 2020-11-25

11 DOSIMETRY (IF APPLICABLE) Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUICALS (IF APPLICABLE) Not applicable