PROFESSIONAL INFORMATION LEAFLET: OPTIPHEN®

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE

OPTIPHEN® 0,5 % Ophthalmic Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of OPTIPHEN 0,5 % Ophthalmic Solution contains 5 mg chloramphenicol and 0,002 % *w/v* phenylmercuric nitrate as preservative.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ophthalmic Solution.
A bright, colourless to faint yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OPTIPHEN is indicated in the treatment of superficial infections of the eye and eyelid, including conjunctivitis, uveitis, corneitis, blepharitis and trachoma.

4.2 Posology and method of administration

Posology:

Adults and children (including the Elderly):
The recommended dose is 2 drops in the affected eye(s) 4 times a day.

Paediatric population:
Dosage adjustment may be necessary in new-born 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 to 14 days.

Method of administration:

For ophthalmic use only.

4.3 Contraindications

- Hypersensitivity to the active substance, chloramphenicol or to 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.
- Pregnancy and lactation (See section 4.6).

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.

If OPTIPHEN is 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 OPTIPHEN 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.

Do not use for more than 5 days.

Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms 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 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 another eye drop or eye ointment
• Contact lens use

Soft contact lenses should not be worn during treatment with OPTIPHEN Ophthalmic Solution 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.

Phenylmercuric nitrate is irritating to the skin. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy.

4.5 Interaction with other medicines and other forms of interaction

The concomitant administration of OPTIPHEN with other medicines liable to depress bone marrow function should be avoided.
OPTIPHEN is inactivated in the liver and may, therefore, interact with medicines that are metabolised by hepatic microsomal enzymes.
OPTIPHEN enhances the effects of coumarin anticoagulants, warfarin, some hypoglycaemics such as chlorpropamide and tolbutamide, and antiepileptics such as phenytoin.
The metabolism of OPTIPHEN may be increased by inducers of hepatic enzymes such as phenobarbitone or rifampicin.
Since OPTIPHEN is absorbed systemically, the following interactions is a possibility:

- OPTIPHEN may decrease the effects of iron and vitamin B_{12} in anaemic patients.
- OPTIPHEN may impair the action of oral contraceptives.

4.6 Fertility, 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 medicine is not recommended for use during pregnancy and lactation.
OPTIPHEN may impair the action of oral contraceptives.
(See section 4.3)

4.7 Effects on 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

System Organ Class	**OPTIPHEN Side Effects**
Blood and lymphatic system disorders	
Less frequent:	Bone marrow depression, aplastic anaemia
Immune system disorders	
Less frequent:	Hypersensitivity reactions including angioedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis.
Eye disorders	
Less frequent:	Transient irritation, burning, stinging and sensitivity reactions such as itching and dermatitis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions. Suspected adverse reactions can be reported to Gen-Eye (Pty) Ltd via email: pharmacovigilance@gen-eye.co.za or telephonically on 011 312 3812. Suspected adverse reactions can also be reported to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form," found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Accidental ingestion of the drops is unlikely to cause systemic toxicity due to the low content of the antibiotic in the medicine. 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

Category and Classification:

Pharmacotherapeutic group: Antibiotics

ATC code: S01AA01

A.15.1 Ophthalmic Preparations with antibiotics and/or sulphonamides.

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, rickettsiae and the trachoma bacterium (chlamydia trachomatis), the main pathogens responsible for acute bacterial conjunctivitis.
Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.
OPTIPHEN does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

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

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax
Boric acid
Phenyl mercuric nitrate (as preservative)
Water for injection

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened: 2 years
Opened: 28 days

6.4 Special precautions for storage

Store in a refrigerator at a temperature between 2 ºC and 8 ºC.
Do not use more than 28 days after opening (see section 6.3).

6.5 Nature and contents of container

Low density polyethylene bottle with polystyrene spiked cap. Available in a pack size of 10 ml.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Gen-Eye (Pty) Ltd[1]
Royal Palm Business Estate
Unit 7, 646 Washington Street
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Gauteng, South Africa

8. REGISTRATION NUMBER(S)

47/15.1/0254

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 March 2021

10. DATE OF REVISION OF THE TEXT

Not applicable

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[1] Company Registration number.: 2009/009360/07