SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Optrex Infected Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 0.5% w/v.

Excipients with known effect: Phenylmercuric nitrate, Boric Acid (and Borates) (0.115 mg boron/drop)

For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution. A clear, slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acute bacterial conjunctivitis.

4.2 Posology and method of administration

Posology

Adults:

One drop instilled into the infected eye every 2 hours for the first 48 hours and 4 hourly thereafter. To be used during waking hours only. The course of treatment is 5 days. Treatment should continue for 5 days even if symptoms improve.

If symptoms persist or worsen after 48 hours, or have not resolved within 5 days, consult a healthcare professional.

Paediatric Population:

Children aged 2 years and over: As above for adults.

Children under 2 years: this product is not recommended for children under 2 years of age.

Elderly:

No dosage adjustments are required for elderly

Method of administration:

For ocular use.

4.3 Contraindications

Chloramphenicol eye drops must not be administered to:

- Patients who have a history of hypersensitivity to chloramphenicol or to any other ingredient of the drops.
- Patients with pre-existing bone-marrow depression or patients who have experienced myelosuppression during previous exposure to chloramphenicol.
- Patients with a family history of blood dyscrasias.

4.4 Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported (see section 4.8).

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.

The use of topical chloramphenicol may occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the patient should be referred to the doctor.

Prolonged or frequent intermittent topical application of chloramphenicol should be avoided since it may increase the likelihood of sensitisation and emergence of resistant organisms.

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

Toxic epidermal necrolysis have been reported very rarely in association with the use of chloramphenicol (see section 4.8).

<u>The label will state:</u>

- 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

For external use only.

Keep all medicines out of the sight and reach of children.

Phenylmercuric nitrate may cause allergic reactions. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy.

Patients should be referred to a 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

If this product is used following advice from a contact lens practitioner or doctor contact lenses should not be worn during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Bone marrow depressant drugs

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of chloramphenicol eye drops during pregnancy has not been established. As this product is for sale without prescription it is not recommended for use during pregnancy.

Breast-feeding

In view of the fact that chloramphenicol/metabolites are excreted in human milk and effects have been shown in breastfed newborns/ infants of treated women, the product should not be used during lactation.

Fertility

No data on human fertility are available.

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 their vision is clear.

4.8 Undesirable effects

Adverse events which have been associated with topical chloramphenicol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Not known	Bone marrow failure[1], aplastic anaemia[1,2]
Immune System Disorders	Not known	Hypersensitivity[3]
Eye Disorders	Not known	Vision blurred, eye pain, eye swelling, eye irritation
Skin and Subcutaneous Tissue Disorders	Not known	Rash vesicular, rash maculo-papular

Description of Selected Adverse Reactions:

[1] Bone marrow failure, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

[2] This can include neutropenia and thrombocytopenia.

[3] This can include rashes, fever, angioedema, urticaria and anaphylaxis. Treatment must be discontinued immediately in such cases.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Symptoms

In view of the relatively small amount of chloramphenicol in chloramphenicol eye drops, overdosage with this product is unlikely to constitute a hazard. Localised symptoms such as eye irritation, pain or swelling, lacrimation or photophobia may occur.

Management

If excess product is applied to the eye the eye should be washed out with water and symptomatic treatment given.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sensory organs; Ophthalmologicals; Antiinfectives; Antibiotics; Chloramphenicol;

ATC Code: S01AA01

Chloramphenicol is a broad spectrum bacteriostatic antibiotic active against a wide variety of gram-negative and gram-positive organisms.

Mechanism of action

Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis at an early stage.

Susceptibility

The following bacterial species are recognised conjunctival pathogens and may be susceptible to chloramphenicol. However due to the prevalence of acquired resistance to chloramphenicol in these species, the results of susceptibility testing should be taken into account if these are available. If no susceptibility test result is available, the choice of antibacterial agent should be influenced by local information on the likely prevalence of resistance to chloramphenicol in species that are commonly pathogenic in the eye.

Staphylococcus aureus

Streptococcus pyogenes

Streptococcus pneumoniae

Other beta-haemolytic streptococci

Haemophilius influenze
Moraxella catarrhalis
Neisseria gonorrhoeae

Resistance

Acquired resistance to chloramphenicol has been described in all the above species. Most commonly this is mediated by bacterial production of a chloramphenicol acetyl transferase that inactivates the drug. Chloramphenicol is not generally active against the enterobacteriaceae and is not active against non-fermenters such as Pseudomonas aeruginosa.

5.2 Pharmacokinetic properties

Following topical application to the eye, chloramphenicol may be absorbed into the aqueous humour. Sufficient chloramphenicol may be absorbed from the eye to appear in the systemic circulation.

Specific data on systemic absorption from this dosage presentation is not available.

Chloramphenicol is readily absorbed when given by mouth. Blood concentrations of 10µg per ml or more may be reached about 1 or 2 hours after a single dose of 1g by mouth, and blood concentrations of about 18.5µg per ml have been reported after multiple 1g doses. Choramphenicol palmitate is hydrolysed to chloramphenicol in the gastrointestinal tract prior to absorption, and the sodium succinate, which is given parenterally is probably hydrolysed to free drug mainly in the liver, lungs, and kidneys; such hydrolysis may be incomplete in infants and neonates, contributing to the variable pharmacokinetics in this age group. Chloramphenicol sodium succinate is, even in adults, only partially and variably hydrolysed, so that blood concentrations of chloramphenicol obtained after parenteral administration of the sodium succinate are often lower than those obtained after administration of chloramphenicol by mouth, with up to 30% of a dose excreted unchanged in the urine before hydrolysis can take place.

Chloramphenicol is widely distributed in body tissues and fluids; it enters the cerebrospinal fluid, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the foetal circulation, into breast milk, and into the aqueous and vitreous humours of the eye. Up to about 60% in the circulation is bound to plasma protein. The half-life of chloramphenicol has been reported to range from 1.5 to 4 hours; the half-life is prolonged in patients with severe hepatic impairment and is also much longer in neonates. Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites.

Chloramphenicol is excreted mainly in the urine but only 5 to 10% of an oral dose appears unchanged; the remainder is inactivated in the liver, mostly by conjugation with glucorinic acid. About 3% is excreted in the bile. However, most is reabsorbed and only about 1%, mainly in the inactive form, is excreted in the faeces.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetics in a given patient.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax powder

Boric acid powder

Phenylmercuric nitrate

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months unopened.

Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.

6.4 Special precautions for storage

Store at 2° to 8°C.

Protect from light.

6.5 Nature and contents of container

The product will be packed in a capped bottle consisting of an opaque white Low Density Polyethylene (LDPE) bottle and dropper nozzle insert, with an opaque, screw on Polypropylene (PP), dropper cap with tamper evident band.

Pack size: 10 ml.

6.6 Special precautions for disposal

None

7. MARKETING AUTHORISATION HOLDER

Optrex Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00062/0051

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 March 2004

10 DATE OF REVISION OF THE TEXT

14/03/2025