# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 0.5% w/v Antibiotic Eye Drops

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 0.5% w/v

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Eye Drops, solution

Clear, colourless to slightly yellow solution

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Chloramphenicol is broad spectrum antibiotic indicated in both adults and children aged 2 years and over for the treatment of acute bacterial conjunctivitis.

### 4.2 Posology and method of administration

Posology

Adults (including the elderly) and children aged 2 years and over:

- Put one drop into the affected eye(s) every 2 hours for the first 48 hours and 4 hourly thereafter.
- To be used during waking hours only
- The course of treatment should be 5 days.

Method of administration

For ocular use.

## 4.3 Contraindications

Chloramphenicol eye drops must not be administered to patients who have:

- Hypersensitivity to the chloramphenicol or to any of the excipients listed in section 6.1.
- Myelosuppression during previous exposure to chloramphenicol.
- Family or personal history of blood dyscrasias including aplastic anaemia.

## 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 use of chloramphenicol eye drops is not advisable. 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.

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

- Seek further immediate medical advice any time if symptoms worsen.
- Consult your doctor if your eye infection does not start to improve within 48 hours.
- Discard the medicine after a 5 day course of treatment.
- Do not use if you are allergic to chloramphenicol or any of the ingredients.
- For external use/use in the eye only
- Keep all medicines out of the sight and reach of children.

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 patient has glaucoma
- 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 period of treatment

Soft contact lens wearers should wait 24 hours after completing a course of treatment before starting to use their lenses again.

Phenylmercuric nitrate is irritant to the skin. Topical application to eyes has been associated with 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 bone marrow function should be avoided.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of chloramphenicol eye drops during pregnancy and lactation 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 may appear in breast milk, use of the product during lactation should be avoided.

Fertility
No fertility data are available.

**4.7 Effects on ability to drive and use machines**

The use of the eye drops may cause transient blurring of vision. Patients should not drive or operate hazardous machinery unless 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 and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Blood and lymphatic system disorders
Bone marrow depression, 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.

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 Yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

**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.

In view of the relatively small amount of chloramphenicol in Chloramphenicol Eye Drops, overdosage with this product is unlikely to constitute a hazard.

No specific treatment would be required. 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

Pharmacotherapeutic group: Ophthalmological antibiotics

ATC code: S01AA01

Chloramphenicol is a broad-spectrum antibiotic with bacteriostatic activity which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

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

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

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Borax
Boric Acid
Phenylmercuric Nitrate
Purified Water

## 6.2 Incompatibilities

None known

## 6.3 Shelf life

Unopened: 24 months

## 6.4 Special precautions for storage

Store upright at 2°C to 8°C in a dry place away from strong sunlight and do not freeze (for example keep in a fridge).
Store in the original carton to protect from light.

## 6.5 Nature and contents of container

Low density polyethylene bottle and dropper insert with high density polyethylene cap. There is a tamper evident seal, which is broken when the bottle is first opened. After cap is removed, if the tamper evident snap collar is loose, please remove before using the product. Take care not to touch the end of the nozzle.

Fill volume is 10ml. Each bottle is then packed into a carton with a patient information leaflet.

## 6.6 Special precautions for disposal

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

# 7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.

Bampton Road
Harold Hill
Romford
Essex
RM3 8UG
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 00156/0109

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20/11/2009

## 10 DATE OF REVISION OF THE TEXT

28/05/2025