

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 0.5% w/v Eye Drops.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of the drops contains 5mg of chloramphenicol (0.5% w/v)

### Excipients with known effect

Contains Phenylmercuric Nitrate 0.02mg/ml (0.002% w/v).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear aqueous solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Chloramphenicol is a broad spectrum antibiotic for the treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms including: *Escherichia coli*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus, haemolyticus*, *Morax-axenfeld*, Klebsiella/Enterobacter species and others.

Chloramphenicol is indicated in both adults and children.

### 4.2 Posology and method of administration

#### Posology

#### Adults, including the elderly and children

One or two drops applied to each affected eye up to 6 times daily or more frequently if required.

#### 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. The maximum duration of treatment is 10-14 days.

#### Method of administration

Eye Drops for topical administration

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- a 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 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 this compound. Where chloramphenicol is used on a long-term of intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect haemopoietic abnormalities.

In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. The prolonged use of antibiotics can cause sensitisation and occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during 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. It is also recommended that all types of contact lens are avoided during an ocular infection.

Chloramphenicol Eye Drops does not provide adequate coverage against *Pseudomonas aeruginosa* 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 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 other eye drops or eye ointment
- Contact lens use

Soft contact lenses should not be worn during treatment with chloramphenicol eye drops 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. If you wear soft contact lenses do not start wearing them for at least 24 hours after you have finished using the eye drops.

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 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

Safety for use 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

Chloramphenicol has a minor influence on the 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 reactions reported in clinical trials and in the post-marketing period are included in the table below. The frequencies correspond with:

Not known (cannot be estimated from the available data)

<b>Blood &amp; lymphatic system disorders</b> Not known	Aplastic anaemia*, bone marrow failure*
<b>Immune system disorders</b> Not known	Anaphylactic reaction*
<b>Nervous system disorders</b> Not known	Burning sensation
<b>Skin and subcutaneous tissue disorders</b> Not known	Angioedema*, dermatitis* (including vesicular & maculopapular dermatitis) urticaria
<b>General disorders and administration site conditions</b> Not known	Pain (stinging sensation), pyrexia*

\*Causes for discontinuation

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 16764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

4.9 Overdose

Accidental ingestion of chloramphenicol eye drops is unlikely to cause systemic toxicity due to the low content of antibiotic. 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: Antibiotics

ATC 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

Evidence suggests that chloramphenicol is absorbed systemically via topical ocular administration. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, is secreted in saliva, with the highest concentrations occurring in the kidneys and liver.

Chloramphenicol also diffuses across the placenta into the foetal circulation and into breast milk.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half life of 1.5 to 5 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours.

### 5.3 Preclinical safety data

No additional data of relevance to the prescriber.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Borax  
Boric acid  
Phenylmercuric nitrate  
Purified water

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

2 years unopened.  
28 days once opened.

### 6.4 Special precautions for storage

Store at 2-8°C. Protect from light.  
Once opened do not store above 25°C.

**6.5 Nature and contents of container**

White polyethylene eye dropper bottle with integral eye drop insert. Fitted with tamper evident white polyethylene cap. Pack size 10 ml.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Sterile until opened.  
Discard 28 days after opening.

**7 MARKETING AUTHORISATION HOLDER**

Martindale Pharmaceuticals Ltd  
Bampton Road  
Harold Hill  
Romford RM3 8UG  
England

**8 MARKETING AUTHORISATION NUMBER**

PA 0361/013/001

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

Date of first authorisation:        26 January 2001  
  
Date of last renewal:                26 January 2006

**10 DATE OF REVISION OF THE TEXT**

August 2017