

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 1% w/w Eye Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of ointment contains 10 mg of chloramphenicol (1% w/w).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye Ointment.

Smooth yellow ointment of firm consistency with a slight odour of wool fat.

## 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

The eye ointment is to be applied every 3 hours or more frequently, if required. Alternatively, when used in conjunction with other treatments, the ointment may be applied at night with appropriate eye drops or other treatment used during the day.

#### 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 Ointment for topical administration. A thin line of ointment to be placed along the inside of the lower lip.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with a known personal or family history of blood dyscrasias including aplastic anaemia should avoid use of this product.

### 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 or intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect haemopoietic abnormalities.

Optic atrophy has been reported following a long term use of chloramphenicol.

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.

Chloramphenicol does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*. It is also recommended that all types of contact lens are avoided during an ocular infection.

#### 4.5 Interaction 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 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 ointment 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 ointment and patients should be warned not to drive or operate machinery unless 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 HPRC 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 ointment 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**

Liquid paraffin  
Wool fat  
Yellow soft paraffin

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

36 months unopened.  
28 days once opened.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Polyethylene tube. Fitted with tamper evident white polyethylene cap.Pack size 4 g.

**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**

Discard 28 days after opening.

**7 MARKETING AUTHORISATION HOLDER**

Ethypharm  
194 Bureaux de la Colline - Bâtiment D  
92213 Saint-Cloud Cedex  
France

**8 MARKETING AUTHORISATION NUMBER**

PA0549/025/002

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

Date of first authorisation: 26 January 2001

Date of last renewal: 26January 2006

**10 DATE OF REVISION OF THE TEXT**

June 2019