

### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

#### 1.3.1.1 NAME OF THE MEDICINAL PRODUCT

International Non- Proprietary Name (INN): Chloramphenicol Eye Drops BP 0.5% w/v.

#### 1.3.1.2 ATC AND FORENSIC CLASSIFICATION

ATC Classification: Broad-spectrum Antibiotic.

ATC Code: ATC code: S01AA01

#### 1.3.1.3 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each ml contains:**

Chloramphenicol BP	0.5%w/v
Phenylmercuric nitrate BP (As preservative)	0.001%w/v
Sterile aqueous base	Q.S.

#### 1.3.1.4 PHARMACEUTICAL FORM

Ophthalmic solution.

Clear, colourless to almost colourless solution filled in a plastic 15 ml vial.

#### 1.3.1.5 CLINICAL PARTICULARS

##### 1.3.1.5.1 Therapeutic Indications

Chloramphenicol is a broad spectrum antibiotic indicated in both adults and children 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.

##### 1.3.1.5.2 Posology and Method of Administration

**Posology:**

Adults and children (including the Elderly)

The recommended dosage for adults and children is two drops to be applied to the affected eye every three hours or more frequently if required. Treatment should be continued for at least 48 hours after eye appears normal.

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.

Administration: For ocular use only.

#### **1.3.1.5.3 Contraindications**

- Hypersensitivity to the active substance , chloramphenicol or to any of the excipients used
- Myelosuppression during previous exposure to chloramphenicol.
- Known personal or family history of blood dyscrasias including aplastic anaemia

#### **1.3.1.5.4 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.

Where chloramphenicol eye drops are 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 chloramphenicol eye drops 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.

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.

#### **1.3.1.5.5 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.

#### **1.3.1.5.6 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 product is not recommended for use during pregnancy and lactation.

#### **1.3.1.5.7 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.

### **1.3.1.5. 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.

#### Blood and lymphatic system disorders:

Bone marrow depression and rarely aplastic anaemia 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.

### **1.3.1.5.9 Overdose**

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

## **1.3.1.6 PHARMACOLOGICAL PROPERTIES**

### **1.3.1.6.1 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.

### **1.3.1.6.2 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.

### **1.3.1.6.3 Preclinical safety data**

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

### **1.3.1.7 PHARMACEUTICAL PARTICULARS**

#### **1.3.1.7.1 Incompatibilities**

Not Known

#### **1.3.1.7.2 Shelf life**

36 Months

#### **1.3.1.7.3 Special precautions for storage**

Store at below 30°C at dry place, protected from light.

#### **1.3.1.7.4 Nature and contents of container**

Clear, colourless to almost colourless solution filled in a plastic 15 ml vial.

#### **1.3.1.7.5 Special precautions for disposal**

Store at below 30°C at dry place after opening. Use the solution within 30 days after opening.

### **1.3.1.8 Registrant**

**M/s MARK PHARMACEUTICALS LIMITED,**

6, Ademulegun Street, Off Godwin Omonua Street, Iri-Akari Estate,  
Isolo, Nigeria

Contact No. +234-8033349224

Email: [markpharmltd@yahoo.com](mailto:markpharmltd@yahoo.com)