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| | **MODULE 1**<br>**ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION** |
| **Mb Chlor Eye Drops**<br>**Chloramphenicol BP 0.5%w/v** | |
| **Module 1 Administrative Information and Product Information**<br>**Section 1.3.1** Summary of Product Characteristics(SmPC) | |

# 1.3.1 Summary of Product Characteristics (SmPC)

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## 1.3 PRODUCT INFORMATION:

### 1.3.1 Summary of Product Characteristics (SmPC)

## 1.NAME OF THE MEDICAL PRODUCT

**1.1** **Product Name:** Mb-Chlor Eye Drops (Chloramphenicol BP 0.5%)
**1.2** **Strength :** Chloramphenicol 0.5%
**1.3** **Pharmaceutical Dosage Form :** Ophthalmic Suspension (Eye drops)

## 2. QUALITATIVE & QUANTITATIVECOMPOSITION

Choramphenicol BP.....0.5%w/v

Sterile aqeous vehicle.....qs

For Full details of excipients refer section 6.1 of SmPC

## 3. PHARMACEUTICAL FORM

Ophthalmic Solution (Eye drops)

Clear colorless sterile solution

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of acute bacterial conjunctivitis.

### 4.2 Posology and method of administration

For ocular use.

The recommended dosage for adults (including the elderly) and children aged 2 years and over is one drop to be applied to the affected eye every two hours for the first 48 hours and 4 hourly thereafter. To be used during waking hours only.

Treatment should continue for 5 days, even if symptoms improve.

### 4.3 Contraindications

Chloramphenicol eye drops should not be administered to patients hypersensitive to Chloramphenicol or any other ingredients in the formulation, or given to those with a known personal or family history of blood dyscrasias including aplastic anaemia.

### 4.4 Special warnings and precautions for use

Prolonged use of Chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms.

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

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 treatment.

The labels will state:

• If symptoms do not improve within 48 hours talk to your doctor.

• Seek further immediate medical advice at any time if symptoms worsen.

• Discard any remaining eye drops after the five day course of treatment.

• Do not use if you are allergic to Chloramphenicol or any of the other ingredients.

**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 Pregnancy and lactation**

The safety of Chloramphenicol Eye Drops during 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 eye drops may cause transient blurring of vision when applied to the eye. Patients should be warned not to drive or operate hazardous machinery unless their vision is clear.

**4.8 Undesirable effects**

Eye disorders:

Chloramphenicol eye drops may cause transient stinging and irritation when applied to the eye.

Blood and lymphatic system disorder:

Bone marrow depression, including irreversible and fatal 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.

Immune system disorders:

Hypersensitivity reactions including angioedema.

### 4.9 Overdose
Not applicable.

## 5.PHARMACOLOGICAL PROPERTIES
### 5.1 Pharmacodynamic Properties:

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of Gram-negative and Gram-positive organisms.

### 5.2 Pharmacokinetic properties
Not applicable to a topical (ophthalmic) preparation.

### 5.3 Preclinical safety data
Preclinical safety data does not add anything of further significance.

## 6. PHARMACEUTICAL PARTICULARS
### 6.1 List of Excipients:
Chloramphenicol BP, Phenyl mercuric nitrate BP, Borax BP, Boric acid BP Distilled water BP

### 6.2 Incompatibilities:

Not applicable

### 6.3 Shelf life:

24 months from the date of manufacturer

**6.4 Special Precautions for storage:**

Store below 30º C.

**6.5 Nature and contents of container:**

10ml white colored cylindrical shaped, colorless solution filled in 10ml LDP bottle, a carton containing one such bottle along with patient information leaflet.

**6.6 Special precautions for disposal:**

Not Applicable

**7. APPLICANT/MANUFACTURER**

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