

## **PACKAGE INSERT**

### **SCHEDULING STATUS:**

**S4**

### **PROPRIETARY NAME AND DOSAGE FORM**

MINIMS® CHLORAMPHENICOL 0,5 % Eye Drops

### **COMPOSITION**

(per dispensing unit of 0,5 ml)

Chloramphenicol 2,5 mg

### **PHARMACOLOGICAL CLASSIFICATION**

A 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides.

### **PHARMACOLOGICAL ACTION**

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

### **INDICATIONS**

Chloramphenicol is used for the local treatment of acute eye infections caused by susceptible organisms.

### **CONTRAINDICATIONS**

Chloramphenicol should not be used for minor infections or prophylactically, or as a long term treatment for dry eye syndrome.

## **WARNINGS**

Caution should be exercised on administration of chloramphenicol to newborn infants, and when treating anaemic patients. Chloramphenicol should not be used with other drugs which may suppress bone marrow function.

## **DOSAGE AND DIRECTIONS FOR USE**

Adults and children: To be used as directed by the ophthalmologist.

## **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

Local hypersensitivity reactions may occur. Treatment with chloramphenicol should be discontinued immediately.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Not applicable

## **IDENTIFICATION**

Clear, colourless solution.

## **PRESENTATION**

Sterile, single-dose, disposable eye drops in cartons of 20 units, each containing approximately 0,5 ml.

## **STORAGE INSTRUCTIONS**

MINIMS CHLORAMPHENICOL must be stored under refrigeration at 5 °C.

DO NOT FREEZE.

If stored at room temperature, the product has a maximum shelf life of 1 month. KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

E/15.1/223

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

Soflens (Pty) Ltd

254 Hall Street

Centurion

0157

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