PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

MINIMS® CHLORAMPHENICOL 0,5 %

Eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterile preservative-free solution containing 2,5 mg chloramphenicol per dispensing unit of 0,5 ml (0,5 % *m/v*) as the active ingredient.

Excipients with known effect:

MINIMS® Chloramphenicol contains borax (0,12 mg per drop equivalent to 3,0 mg/ml) and boric acid (0,60 mg per drop equivalent to 15 mg/ml).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container

A clear, colourless solution, reasonably free from visible particulate matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Chloramphenicol is indicated in adults and children.

4.2 Posology and method of administration

Adults (including the Elderly)

One to two drops applied topically to each affected eye up to six times daily or more frequently if required. Severe infections may require one or two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled.

Paediatric population

As for adults however, 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.

4.3 Contraindications

- Hypersensitivity to chloramphenicol or any other ingredients (see Section 6.1 List of excipients).
- Chloramphenicol should not be used for minor infections or prophylactically, or as a long-term treatment for dry eye syndrome.

4.4 Special warnings and precautions for use

In severe infections topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

Caution should be exercised when treating anaemic patients. Chloramphenicol should not be used with other medicines which may suppress bone marrow function.

Aplastic anaemia has, rarely, followed topical use of chloramphenicol eye drops and, whilst this hazard is an uncommon one, it should be borne in mind when the benefits of the use of chloramphenicol are assessed.

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms. The maximum duration of treatment is 10-14 days.

Contact lenses should be removed during the period of treatment.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

4.5 Interaction with other medicines and other forms of interaction

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

Safety for use in pregnancy and lactation has not been established.

Systematically absorbed/administered forms of chloramphenicol enter the foetal circulation and are distributed into breast milk. If given systematically to the mother shortly before parturition or whilst breastfeeding, chloramphenicol may cause bone marrow suppression of the neonate or "grey baby syndrome", characterised by cyanosis and hypothermia, owing to the limited glucuronidating capacity of the neonate's liver. However, limited absorption following ophthalmic use at the recommended dosage is generally not expected to pose a risk to the foetus or neonate.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on installation. Warn patients not to drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Local

Local hypersensitivity reactions, such as transient irritation, burning, stinging, itching and dermatitis, may occur. Treatment with chloramphenicol should be discontinued immediately

Systemic

Rarely, cases of major adverse haematological events (bone marrow depression, aplastic anaemia and death) have been reported following ocular use of chloramphenicol. Pale skin, weakness, increased heart rate, out of breath, headache, pain, fever, infection, bruises may be signs of a severe blood disorder.

Hypersensitivity reactions including angioedema, anaphylaxis, urticaria, vesicular and maculopapular dermatitis may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

Suspected adverse reactions may also be reported directly to the Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com

4.9 Overdose

Accidental ingestion of the medicine is unlikely to cause any toxicity due to the low content of antibiotic. MINIMS® Chloramphenicol contain boric acid and borax as a buffer and if ingestion by infants or young children occurs, the poison centre should be contacted.

Treatment

If irritation, pain, lacrimation or photophobia occurs after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmic examination should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

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.

5.2 Pharmacokinetic properties

Chloramphenicol is rapidly absorbed after oral administration. In the liver, chloramphenicol is inactivated by conjugation with glucuronic acid or by reduction to inactive aryl amines. Excretion is mainly renal, though some bile excretion occurs following oral administration.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax, boric acid and purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

30 months

If stored at room temperature, the product has a maximum shelf life of 1 month.

6.4 Special precautions for storage

Store in a refrigerator between 2 – 8 °C.

DO NOT FREEZE.

Protect from light.

If necessary, the product may be stored at room temperature not exceeding 25 °C for up to 1 month only.

6.5 Nature and contents of container

MINIMS® Chloramphenicol eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-of cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polyester/polyethylene laminate sachet. The sachets are packed in cartons of 20 units.

6.6 Special precautions for disposal

Each MINIMS® unit should be discarded after single use.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

E/15.1/223

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 May 1974

10 DATE OF REVISION OF THE TEXT

14 February 2022