Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Chloramphenicol 0.5% Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 0.5% w/v.

Excipients with known effect
Minims Chloramphenicol contains borax and boric acid.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clear, colourless, sterile single use eye drops solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is indicated for the topical treatment of infections due to micro-organisms sensitive to the anti-infective.
Chloramphenicol is indicated in adults and children (above 2 years old).

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 to two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

Paediatric population (children above 2 years old)
As for adults. The maximum duration of treatment is 10 - 14 days.

4.3 Contraindications

Use in patients with a history of hypersensitivity or toxicity to chloramphenicol or any other component of the preparation.

4.4 Special warnings and precautions for use

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

Aplastic anaemia has, very 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.

Chloramphenicol should be reserved for use only in infections for which it is specifically indicated. 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.)

Minims Chloramphenicol should not be given to children less than 2 years old as it contains boron and may impair fertility in the future.

4.5 Interaction with other medicinal products and other forms of interaction

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by the physician.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Local

Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis, may occasionally occur. Systemic Rarely, cases of major adverse haematological events (bone marrow depression, aplastic anaemia and death) have been reported following ocular use of chloramphenicol. 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 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:

HPRA Pharmacovigilance
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chloramphenicol is an antibiotic which is mainly bacteriostatic in action, but exerts a bactericidal effect against some strains of gram-positive cocci and against Haemophilus Influenzae and Neisseria. It has a broad spectrum of action against both gram-positive and gram-negative bacteria, rickettsiae and chlamydia.

Chloramphenicol binds specifically to the 50s subunit of 70s ribosomes, preventing its movement along messenger RNA, which occurs in the early stages of protein synthesis.

Chloramphenicol also inhibits NADH oxidase, affecting the mitochondrial respiratory chain.

5.2 Pharmacokinetic properties

In a study in patients, instillation of chloramphenicol eye drops to the eye (2 drops of a 0.5% solution instilled every 5 minutes for a total of 6 doses, into the eyes of 14 patients) gave concentrations of chloramphenicol of 3.5 - 6.7µg/ml in the aqueous humour.

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 which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax
Boric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store between 2° and 8°C. Do not freeze. Store in the original container, to protect from light.

6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution.

Each carton contains 20 individual Minims units.

6.6 Special precautions for disposal and other handling

Each Minims unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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Dublin 24
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

November 2022