SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minims Chloramphenicol 0.5% w/v, eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing Chloramphenicol Ph Eur 0.5% w/v.

Excipients with known effect:
Minims Chloramphenicol contains borax (0.12mg per drop equivalent to 3.0 mg/ml) and boric acid (0.60 mg per drop equivalent to 15 mg/ml).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sterile single use eye drop.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is a broad spectrum bacteriostatic antibiotic. It is active against a wide variety of gram-negative and gram-positive organisms as well as rickettsiae and spirochaetes. It is indicated for use as a topical antibacterial in the treatment of superficial ocular infections. 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 to 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 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, 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.

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 medicinal products and other forms of interaction

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

4.6 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 installation. 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 occur.

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 a sign 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 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

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 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

None known.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store between 2° and 8°C. Do not freeze. Protect from light.

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

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims Chloramphenicol unit is overwrapped in an individual polyethylene sachet. 20 units each containing 0.5ml are packed into a suitable carton.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use.

If the product is to be stored unrefrigerated at temperatures not exceeding 25°C, prior to supply of the product by the pharmacy the adhesive label provided in the carton should be completed and affixed over the bar code, by a pharmacist. An expiry date one month from the supply date, plus the pharmacist's initials should be written in the spaces provided on this label.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0069

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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