MINIMS CHLORAMPHENICOL 0.5%

Qualitative And Quantitative Composition
Clear, colourless, sterile eye drops containing Chloramphenicol PhEur 0.5% w/v.

Pharmaceutical Form
Sterile single use eye drop.

Clinical Particulars

Therapeutic Indications
Chloramphenicol is indicated for the topical treatment of infections due to micro-organisms sensitive to the anti-infective.

Posology and Method of Administration
Adults (including the Elderly) and Children:

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).

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

Special Warnings and Special 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.)

**Interaction With Other Medicaments and Other Forms of Interaction**

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

**Pregnancy and Lactation**

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

**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.

**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.

**Overdose**

Not applicable.

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**Pharmacological Properties**

**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.

**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.

**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 data sheet.

**Pharmaceutical Particulars**

**List of Excipients**

Borax PhEur
Boric acid PhEur
Purified water PhEur

**Incompatibilities**

None known.

**Shelf Life**

30 months.

**Special Precautions for Storage**

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

**Nature and Contents of Container**

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch.
Instructions for Use/Handling

Each Minims unit should be discarded after a single use.

Medicine Classification

Prescription medicine.

Marketing Authorisation Holder

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