SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 1% w/w Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 10 mg chloramphenicol (1 % w/w).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye ointment.

A yellowish-white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is a broad spectrum antibiotic for the treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms.

Chloramphenicol is indicated in both adults and children.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Adults:

The recommended dosage for adults is a small amount of the ointment to be applied to the affected eye every 3 hours or more frequently if required. Treatment should be continued for 48 hours after the eye appears normal.

Paediatric population under 18 years of age

As for adults. However, dose 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.

Elderly:

As for adults. Chloramphenicol has been used successfully at normal dosages in elderly patients. The pattern and incidence of adverse effects does not appear to differ from younger adults.

Method of administration

For topical administration to the eye only.

4.3 Contraindications

The ointment must not be administered to:

- Patients who have a history of hypersensitivity to chloramphenicol or to any of the excipients listed in section 6.1.
- Patients who have experienced bone marrow suppression during previous exposure to chloramphenicol.

4.4 Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and systemic toxicity has been reported (see section 4.8).

Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of the compound.

If the eye ointment is to be used on a long-term or intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect any haemopoietic abnormalities.

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment.

Chloramphenicol does not provide coverage against Pseudomonas spp. or serratia marcescens.

The use of topical chloramphenicol may occasionally result in overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate treatment given.

It is recommended that all types of contact lenses be avoided during ocular infections.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided. If a concomitant topical treatment to the eye is required, the administration of the different products should be separated by an adequate period of time.

4.6 Fertility, Pregnancy and lactation

The safety of topical chloramphenicol in pregnancy and lactation has not been established. It should therefore only be used when considered essential by the physician and only if it is considered that the anticipated benefit outweighs the potential risk.

4.7 Effects on ability to drive and use machines

Blurring of vision can occur with the ointment and patients should be warned not to drive or operate machinery unless their vision is clear.

4.8 Undesirable effects

Transient burning or stinging sensations may occur with the use of ophthalmic chloramphenicol. Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases.

Bone marrow suppression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognized to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

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 the Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Accidental overdose or accidental ingestion of the ointment is unlikely to cause systemic toxicity due to low content of chloramphenicol in the product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: S01AA01

Mechanism of Action:
Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis at an early stage.

Susceptibility:
The following bacterial species are recognised conjunctival pathogens and may be susceptible to chloramphenicol. However due to the prevalence of acquired resistance to chloramphenicol in these species, the results of susceptibility testing should be taken into account as soon as these are available. If no susceptibility test result is available, the choice of antibacterial agent should be influenced by local information on the likely prevalence of resistance to chloramphenicol in species that are commonly pathogenic in the eye.
Staphylococcus aureus
Streptococcus pyogenes
Streptococcus pneumoniae
Other beta-haemolytic streptococci
Haemophilius influenzae
Moraxella catarrhalis
Neisseria gonorrhoeae

Resistance:
Acquired resistance to chloramphenicol has been described in all the above species. Most commonly this is mediated by bacterial production of a chloramphenicol acetyl transferase that inactivates the drug. Chloramphenicol is not generally active against the enterobacteriaceae and is not active against non-fermenters such as *Pseudomonas aeruginosa.*

5.2 Pharmacokinetic properties

Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.

Systemic exposure to chloramphenicol occurs at a very low level after topical ophthalmic use.

5.3 Preclinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
Shelf life after first opening of the tube: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and contents of container

Aluminium tube with epoxy-phenolic-ureic resin internal coating.

Polyethylene screw cap and nozzle.

Pack size 4g tube

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 14308/0018

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/03/2016

10 DATE OF REVISION OF THE TEXT

14/11/2023