SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol Eye Ointment BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For excipients see Section 6.1

3 PHARMACEUTICAL FORM

Eye Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of bacterial conjunctivitis in both adults and children, caused by the organisms Escherichia coli, Haemophilus influenzae, Staphylococcus aureus, Streptococcus haemolyticus, Morax-Axenfield and others.

4.2 Posology and method of administration

The recommended dosage for adults, children and infants of all age groups is a small amount of ointment to be applied to the affected eye every three hours or more frequently if required. Treatment should be continued for at least 48 hours after eye appears normal.

Paediatric population

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 Contra-indications

Hypersensitivity to chloramphenicol or any of the excipients listed in section 6.1.

Patients who have experienced myelosuppression during previous exposure to chloramphenicol.

Patients with a family history of blood dyscrasias.

4.4 Special warnings and precautions for use

Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure. 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. Where chloramphenicol eye ointment is 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 haemopoietic abnormalities.

In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. The prolonged use of antibiotics may occasionally result in overgrowth of non susceptable organisms, including fungi. If any new infection appears during the treatment, the antibiotic should be discontinued and appropriate measures taken. Chloramphenicol should be reserved for use only for infections for which it is specifically indicated. Contact lenses should be removed during treatment.

Chloramphenicol does not provide adequate coverage against Pseudomonas aeruginosa and Serratia marcescens.

It is recommended that all types of contact lenses are avoided during ocular infections. Chloramphenicol eye ointment may smear over the surface of contact lenses.

4.5 Interaction with other medicinal products and other forms of interactions

Bone marrow depressant drugs.

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

Transient blurring of vision may occur immediately after use and driving or using machinery should not occur until the vision is clear.

4.8 Undesirable effects

Transient burning or stinging sensations may occur. More serious side effects include bone marrow depression and rarely aplastic anaemia, angioneurotic oedema,
anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Accidental ingestion of the eye drops is unlikely to cause systemic toxicity due to the low content of the antibiotic in the product. If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If symptoms persist after this, an ophthalmological examination should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms.

5.2 Pharmacokinetic properties

Not applicable to topical (ophthalmic) preparations.

5.3 Preclinical safety data

Nothing of relevance which is not included in other sections of the SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
White petroleum

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened: 48 months
Opened: 28 days

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

4g aluminium tube and polyethylene cap.

6.6 Special precautions for disposal

None stated

7. MARKETING AUTHORISATION HOLDER

Medicom Healthcare Ltd
Lynton House, 7-12 Tavistock Square,
Kings Cross, London,
WC1H 9LT,
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 18956/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/04/2000

10 DATE OF REVISION OF THE TEXT

24/02/2022