1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol 5% w/v Ear Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 5% w/v

Excipient with known effect

1ml contains 0.95g of propylene glycol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ear Drops

Clear, colourless to pale yellow vert slightly viscous liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is a broad spectrum bacteriostatic antibiotic. It is active against a wide range of Gram-negative and Gram-positive organisms, including Salmonella typhi, Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae and Bacteroides fragilis. It has antirickettsial and antichlamydial activity. It is indicated for the topical treatment of bacterial infection of the external ear caused by pathogens which are sensitive to it.

Chloramphenicol is indicated in adults and children.

4.2 Posology and method of administration

Posology

Adults, Children and the Elderly

Apply 3 - 4 drops into the affected ear 2 - 3 times daily for up to 1 week.

Following administration of ear drops patients should be advised to lie down with the affected ear uppermost for a minimum of 10 minutes. After this time cotton wool may be inserted into the ear and normal activities resumed.

Infants

Only use if considered essential by the physician.

Method of administration

For topical use

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

• If the ear drum is perforated.

• Myelosuppression during previous exposure to chloramphenicol.

• Known personal or family history of blood dyscrasias including aplastic anaemia

4.4 Special warnings and precautions for use

Avoid use for more than 1 week as this may result in sensitivity to chloramphenicol or the emergence of resistant organisms. Where chloramphenicol ear drops are 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.

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.

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

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms.

If any new infection appears during the treatment, the antibiotic should be discontinued and appropriate measures taken. Chloramphenicol should be reserved for use only in infections for which it is specifically indicated.

Excipient Warnings

This medicine contains 0.95g of propylene glycol in 1ml which is equivalent to 95% w/v.

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.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established.

Chloramphenicol may be absorbed systemically following the use of ear drops and may cross the placenta and appear in breast milk. Therefore this product is not recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune System Disorders:

Hypersensitivity reactions including angioedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis.

Blood and lymphatic system disorders:

Bone marrow depression and rarely aplastic anaemia 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 this compound. Chloramphenicol may ocassionally cause blood dyscrasia.

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

4.9 Overdose

Overdose is unlikely to occur with this preparation.

Overdose is unlikely to occur with this preparation.

Accidental ingestion of the 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

ATC code: S02AA01

Pharmacotherapeutic group: Otologicals, antibiotic

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms. It acts by interfering with bacterial protein synthesis.

5.2 Pharmacokinetic properties

When used topically systemic absorption is very low. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, is secreted in saliva, with the highest concentrations occurring in the kidneys and liver.

Chloramphenicol also diffuses across the placenta into the foetal circulation and into breast milk.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half life of 1.5 to 5 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours in the latter.

5.3 Preclinical safety data

There is no pre-clinical safety data of relevance to the prescriber, therefore, none is presented in this section.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months (unopened).

28 days once opened

6.4 Special precautions for storage

Store at 2-8°C in a dry dark place. Do not freeze.

6.5 Nature and contents of container

A 10ml low density polyethylene bottle with dropper insert and high density polyethylene tamper evident cap. After cap is removed, if the tamper evident snap collar is loose, please remove before using the product. Take care not to touch the end of the nozzle.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd

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8. MARKETING AUTHORISATION NUMBER(S)

PL 00156/0050

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th June 1997

Date of latest renewal: 2nd February 1998

10 DATE OF REVISION OF THE TEXT

08/08/2025