## 1 NAME OF THE MEDICINAL PRODUCT

Chloramphenicol ear drops
(Chloramphenicol 5% $^{w}/_{v}$)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol(Bulk), Benzalknium chlorde 95%, Propylene glycol, Distilled water.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution/Ear Drops

## 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 treatment of bacterial infection of the external ear caused by pathogens which are sensitive to it.

### 4.2 Posology and method of administration

Posology

Ear drops: 2 to 3 drops 2 to 3 times daily.

Method of administration
Otic route

### 4.3 Contraindications

Choramphenicol is contraindicated in patients with a history of haematological disorders and in neonates.

### 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.

### 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 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.

### 4.9 Overdose

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

Pharmacotherapeutic group: Otologicals, antibiotic

ATC code: S02AA01

Mechanism of action

Chloramphenicol is lipid-soluble, allowing it to diffuse through the bacterial cell membrane. It then reversibly binds to the L16 protein of the 50S subunit of bacterial ribosomes, where

transfer of amino acids to growing peptide chains is prevented (perhaps by suppression of peptidyl transferase activity), thus inhibiting peptide bond formation and subsequent protein synthesis. Chloramphenicol is a broad spectrum antibiotic active against most gram-negative and some gram-positive microorganisms, rickettsiae, chlamydia, mycoplasma and the causing agents of brucellosis.

### 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
Benzalkonium chloride 95%
Distilled water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months (unopened).

28 days once opened

### 6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

### 6.5 Nature and contents of container

Choramphenicol Ear drops is avialable in sterile lupolen bottle containing 10ml of the drops.

### 6.6 Special precautions for disposal <and other handling>

No special requirements for disposal and other handling.

## 7. APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
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## 8. MARKETING AUTHORISATION NUMBER

04 – 7829

## 9. DATE OF FIRST AUTHORIZATION

21/12/2005

## 10. DATE OF REVISION OF THE TEXT

05/2023