

SUMMARY OF PRODUCT CHARACTERISTICS

CHLORAMPHENICOL EAR DROPS B.P 5.0% w/v (ABCHLOR EAR DROPS)

1. Name of the medicinal product

Chloramphenicol 5.0% w/v Ear Drops (ABCHLOR Ear drops)

2. Qualitative and quantitative composition

Chloramphenicol 5% w/v

Excipient(s) with known effect:

Propylene Glycol B.P

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Ear drops, solution.

Aqueous, clear, faintly yellow solution.

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

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4.2 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.

4.3 Special warnings and special 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 propylene glycol.

4.4 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.

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4.5 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

4.6 Effects on ability to drive and use machines

None known.

4.7 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 occasionally 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

4.8 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.

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5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Otologicals, antibiotic

ATC code: S02AA01

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
- Phenyl Mercuric Nitrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 36 months

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Use within 28 days of first opening

Discard four weeks of first opening

6.4 Special precautions for storage

Do not store above 30°C and do not freeze.

6.5 Nature and contents of container

Low density polyethylene dropper bottles and a white screw cap in pack sizes of 5mL and 10mL.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder

Abacus Parenteral Drugs Limited

Block 191, Plot no.114, Kinga Mukono

P.O.Box 31376, Kampala, Uganda.

Email: apdl@abacuspharma.com

Website: www.abacuspenteral.com

8. Marketing authorization number(s)

N/A

9. Date of first authorization/renewal of the authorization

First authorization: 2011

Renewal of authorization: 2017

10. Date of revision of the text

N/A