SUMMARY OF PRODUCT CHARACTERISTICS

CHLORAMPHENICOL EYE DROPS (ABCHLOR Eye drops)

1. Name of the Medicinal Product

Chloramphenicol eye Drops (ABCHLOR Eye drops)

2. Qualitative and Quantitative Composition

Each 1ml of solution contains 5mg Chloramphenicol.

3. Pharmaceutical Form

Ophthalmic drops
It is a clear colourless to faintly yellow solution.

4. Clinical Particulars

4.1 Therapeutic Indications

Treatment of bacterial conjunctivitis caused by the organisms; Escherichia coli, Haemophilusinfluenzae, 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 two drops to be applied to the affected eye every three hours or more frequently if required. Treatment should be continued for atleast 48 hours after eye appears normal.

4.3 Contraindications

• Hypersensitivity to chloramphenicol or to any other ingredient of the drops.

• Myelosuppression during previous exposure to chloramphenicol.

• Family history of 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 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.

• 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.

• Soft contact lenses should not be worn during treatment with chloramphenicol eye drops due to absorption of the preservative onto the lens which may cause damage to the lens. 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.

Bone marrow suppressant drugs.

4.6 Pregnancy and Lactation

Safety in pregnancy and lactation has not yet been established.

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

Eye disorders:

Transient irritation, burning, stinging and sensitivity reactions such as itching and dermatitis.

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.

4.9 Overdose

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.

SUMMARY OF PRODUCT CHARACTERISTICS

CHLORAMPHENICOL EYE DROPS (ABCHLOR Eye drops)

If symptoms persist after this, an ophthalmological examination should be considered

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antibiotics

ATC code: S01AA01

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms including Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus viridans, Moraxella species and Enterobacteriaceae, the main pathogens responsible for acute bacterial conjunctivitis. Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.

5.2 Pharmacokinetic Properties

Chloramphenicol is an extremely well established antibiotic and the successful use of the eye drops is well documented. Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.

6. Pharmaceutical Particulars

6.1 List Of Excipients

- Phenyl mercuric nitrate B.P.
- Boric acid B.P
- Borax B.P
- Disodium edetate
- Water for Injections B.P.

6.2 Incompatibilities

None

6.3 Shelf Life

Un opened: 36 months

Opened: 28days

SUMMARY OF PRODUCT CHARACTERISTICS

CHLORAMPHENICOL EYE DROPS (ABCHLOR Eye drops)

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

10ml and 5ml sealed transparent plastic ampoules, packed in baby cartons.

6.6 Special precautions for disposal and other handling

Use as directed by the physician.

Keep out of reach of children.

7. Marketing Authorization Holder

Abacus Parenteral Drugs Ltd. Uganda

Block 191, Plot no.114, Kinga Mukono

P.O.Box 31376, Kampala, Uganda.

8. Marketing Authorization Number(s)

8510/21/13

9. Date of first authorisation/renewal of the authorisation

September 2013

10. Date of revision of the text

13/04/19