

Only for the use of Medical Professionals

ICOL[®]

Eye & Ear Drops

Presentation

ICOL[®] is a clear colourless ophthalmic solution of Chloramphenicol that is sterile until the bottle is opened. Each ml **ICOL[®]** Eye & Ear Drops contains Chloramphenicol BP 5 mg.

Description

Chloramphenicol is a potent, broad spectrum antibiotic which is effective against a wide range of gram-positive and gram-negative bacteria and also effective against *Spirochaete*, *Salmonella*, *Rickettsiae* and *Chlamydiae* (*trachoma*). Chloramphenicol is primarily a bacteriostatic, readily penetrates into bacterial cells and acts by inhibition on protein synthesis by interfering with the transfer of activated amino acids from soluble RNA to ribosomes. It has been noted that Chloramphenicol is found in measurable amounts in the aqueous humor following local application to the eye.

Use

As a broad spectrum antibiotic **ICOL[®]** can be used in a variety of infections caused by susceptible organisms, such as conjunctivitis, blepharitis, corneal ulcer, dacryocystitis etc. **ICOL[®]** is active against the common bacterial eye pathogens listed below:

Staphylococcus aureus, *Streptococci* including *Streptococcus pneumoniae*, *E.coli*, *Haemophilus influenzae*, *Klebsiella/Enterobacter* species, *Neisseria* species, *Moraxella lacunata*.

Chloramphenicol can destroy or inhibit the susceptible organisms present in the ear canal.

Dosage and Administration

Eye

Two drops applied to the affected eye every three hours, or more frequently if deemed advisable by the prescribing physician. Administration should be continued day and night for the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye appears normal.

Ear

2-3 drops into the ear canal twice or thrice daily.

Paediatric Use

No specific data are available and thus no specific dosage recommendation can be given.

Contra-Indications, Warnings etc.

Contra-indications: Hypersensitivity to the ingredients, acute intermittent porphyria, severe blood disorders and hepatic dysfunctions due to the bone marrow depression, new-born, family history of bone marrow depression.

Precautions: The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections appear during medication, the drug should be discontinued and appropriate measures should be taken.

Pregnancy: Animal experiments with Chloramphenicol have shown adverse effects on the fetus. **ICOL®** should not be given to pregnant women or new-born.

NursingMother: Due to adverse effect **ICOL®** should not be given to nursing mother.

Side-Effects: Shortly after application a slight burning sensation and a bitter taste in the mouth may occur. Allergic reactions in the form of palpebral eczema have been reported in rare cases. Partially irreversible hematodyscrasia (aplastic anaemia, pancytopenia, Leukopenia, thrombocytopenia, agranulocytosis) has been Observed in isolated cases following topical use of Chloramphenicol.

Drug Interactions: Systemic drug interactions have not been documented with the ophthalmic use of Chloramphenicol. But it is essential to observe for the known systemic drug interactions (tolbutamide, phenytoin, paracetamol and preservatives etc.).

Directions for Use

The following steps should be considered to ensure the right use of **ICOL®**

- a. Proper administration technique for applying the solution to the eye and ear.
- b. Compliance with full course of therapy.
- c. Missed dose: Applying as soon as possible; not applying if almost time for the next dose.
- d. Close bottle immediately after use.
- e. Proper storage of the medicament.

Do not use longer than one month after opening. It is advisable to destroy any remaining medicament after completing treatment.

Pharmaceutical Precautions

Store **ICOL®** below 30°C in a tight container; protect from light.

Package Quantities

ICOL®: Dropper bottle of 10 ml.

® Registered Trade Mark



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