

SHINACOL[®] EYE DROPS 0.5%

Ingredient(s):

Each ml contains:

Chloramphenicol.....5mg
Phenylmercuric Nitrate (as preservative).....0.02mg

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetic):**Pharmacodynamic:**

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of Gram-negative and Gram-positive organisms.

Pharmacokinetic:

Chloramphenicol is rapidly absorbed after oral administration. In the liver, chloramphenicol is inactivated by conjugation with glucuronic acid or by reduction to inactivate aryl amines. Excretion is mainly renal, though some bile excretion occurs following oral administration.

Indication(s):

Chloramphenicol is indicated for use as a topical antibacterial in the treatment of superficial ocular infections.

Dosage and Administration(s):

Adults (including the Elderly) and Children 2 years and over: One to two drops applied topically to each affected eye up to 6 times daily or more frequently if required. (Severe infections may require one to two drops every 15 to 20 minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

Mode of Administration(s):

For ocular use.

Contraindication(s):

Chloramphenicol eye drops should not be administered to patients hypersensitive to chloramphenicol or given to those with a known personal or family history of blood dyscrasias including aplastic anaemia.

Warning and Precautions(s):

1. Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms.
2. Do not use for more than 5 days without consulting a doctor.
3. Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time.
4. Patients should be referred to their doctor if any of the following apply:
 - Disturbed vision
 - Severe pain within the eye
 - Photophobia
 - Eye inflammation associated with a rash on the scalp or face
 - The eye looks cloudy
 - The pupil looks unusual
 - Suspected foreign body in the eye
5. Patients should also be referred to their doctor if any of the following in his/her medical history apply:
 - Previous conjunctivitis in the recent past
 - Glaucoma
 - Dry eye syndrome
 - Eye surgery or laser treatment in the last 6 months
 - Eye injury
 - Current use of other eye drops or eye ointment
 - Contact lens use
6. If this product is used following advice from a contact lens practitioner or doctor, contact lenses should not be worn during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing treatment.
7. Phenylmercuric nitrate is irritating to the skin. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy.

Interaction with Other Medicaments(s):

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

Chymotrypsin will be inhibited if given simultaneously with chloramphenicol.

Pregnancy and Lactation(s):

The safety of Chloramphenicol eye drops during pregnancy and lactation has not been established.

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

Side Effects(s):

1. Chloramphenicol eye drops may cause transient stinging and irritation when applied to the eye.
2. Bone marrow depression, including irreversible and fatal 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.

Symptoms and Treatment of Overdose(s):

Not applicable.

Storage Condition(s):

Store at temperature between 2°C to 8°C.

Shelf Life(s):

2 years from the date of manufacture.

Discard 1 month after opening.

Product description & Packing(s):

Plastic bottle of 5ml, 5ml x 10, 5ml x 12, 5ml x 20 & 5ml x 24.

A clear and colorless solution.



Manufacturer and Product Registration Holder :
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