

CHLORAFAST

Chloramphenicol Eye Drops BP 0.5% w/v

Presentation

CHLORAFAST 0.5% eye drop solution is a colourless to faint yellow aqueous solution, containing 5mg/mL chloramphenicol. It also contains 0.02% mg/mL phenyl mercuric nitrate as a preservative.

Uses

Actions

Chloramphenicol is a broad spectrum antibiotic which acts through the inhibition of bacterial protein synthesis by preventing attachment of aminoacyl transfer RNA to its acceptor site on the ribosome. It is bacteriostatic and is effective against a wide range of Gram-positive and Gram-negative bacteria, as well as some other organisms.

Pharmacokinetics

Chloramphenicol is readily absorbed from the gastro-intestinal tract when given orally and is widely distributed in body tissues and fluids.

Chloramphenicol is excreted mainly in the urine but only 5 – 10% of an oral dose appears unchanged; the remainder is inactivated in the liver, mostly by conjugation with glucuronic acid.

Following instillation into the eye the levels in the aqueous humor are in the same order as seen following oral administration with levels in the region 5mcg/mL being seen after repeated applications of 0.5% drops in humans.

Indications

For the treatment of bacterial conjunctivitis and other superficial ocular infections caused by chloramphenicol-sensitive organisms.

Dosage and Administration

Instil 1 or 2 drops in the affected eye(s) every two to six hours for two to three days. The interval between applications may then be increased.

Treatment should be continued for at least 48 hours after the eye appears normal.

The systemic absorption of CHLORAFAST eye drops can be minimised by applying gentle pressure on the tear-duct for approximately one minute immediately after application.

Contraindications

Chloramphenicol is contraindicated in individuals with a history of hypersensitivity to any excipients and/or toxic reaction to the medicine.

Warnings and Precautions

Bone marrow hypoplasia, including aplastic anaemia and death, has been rarely reported following local application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment. Ophthalmic agents may retard corneal wound healing.

The use of this antibiotic, as with other antibiotics, may result in the overgrowth of non-susceptible organisms, including fungi. If infections caused by non-susceptible organisms appear during therapy, its use should be discontinued and appropriate measures should be taken. In all serious infections, the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

Contact lenses should be removed during the period of treatment.

This product is not intended for long term treatment of dry eye syndrome.

Pregnancy and Lactation

Category A

Chloramphenicol enters the foetal circulation, and if given to the mother shortly before parturition, may cause the *gray baby syndrome*, with cyanosis and hypothermia, owing to the limited glucoronidating capacity of the newborn infant's liver. Chloramphenicol treatment should, therefore, be avoided during the last week before parturition and during breast feeding

Effects on ability to drive and use machinery

May cause transient blurring of vision on instillation. Patients should be warned not to drive or operate machines unless vision is clear.

Adverse Effects

Blood dyscrasias have been reported in association with the use of chloramphenicol (see Warnings and Precautions).

Chloramphenicol is absorbed systemically from the eye, and toxicity has been reported following chronic exposure. Dose related toxicity following a single ocular exposure is unlikely.

Local irritation with the ophthalmic form may include subjective symptoms of itching or burning.

More serious side effects such as angioneurotic oedema; anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication. Similar sensitivity reactions to other materials in topical preparations also may occur.

Interactions

Chymotrypsin may be inhibited if given simultaneously with chloramphenicol.

No specific interactions or incompatibilities with other ophthalmically administered medicines are known.

Overdosage

Accidental ingestion of the medicine is unlikely to cause any toxicity due to low content of antibiotic. Each mL of CHLORAFAST eye drops contains 19 mg of borax/boric acid as buffer and if accidentally ingested by infants or young children, a local Poisons Information Centre should be contacted. It is advisable to keep medication out of reach of children.

Treatment

If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmological examination should be considered.

Pharmaceutical Precautions

Store between 2°C and 8°C. Refrigerate, do not freeze.

Do not touch dropper tip to any surface, as this may contaminate the solution.

Discard within 28 days of opening.

Protect from light.

Medicine Classification

Pharmacist Only Medicine.

Package Quantities

CHLORAFAST Eye Drops: 10 mL plastic dropper bottle.

Further Information

Excipients: Phenyl mercuric nitrate, Borax, Boric acid and Water for Injection.

Name and Address

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