

Cyporin

Cyclosporine 0.05%
Sterile Ophthalmic Emulsion

Composition:

Cyporin Sterile Ophthalmic Emulsion : Each ml contains Cyclosporine USP 0.5 mg.

Preservative : Thiomersal BP 0.004%.

Vehicle : Carbomer 980 USNF 0.125%.

Pharmacology:

Cyclosporine is an immunosuppressive agent when administered systemically. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, topical Cyclosporine is thought to act as a partial immunomodulator.

Indications:

Cyporin Ophthalmic Emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with dry eye syndrome (keratoconjunctivitis sicca).

Dosage and Administration:

Instill one drop a day in each eye approximately 12 hours apart. Cyclosporine Ophthalmic Emulsion can be used concomitantly with artificial tears, allowing a 15-minutes interval between products.

Contraindications:

Cyclosporine Ophthalmic Emulsion is contraindicated in patients with active ocular infections and in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Side effects:

The most common adverse event was ocular burning. Other events reported included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Precautions:

Cyclosporine Ophthalmic Emulsion should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of this formulation. Lenses may be reinserted 15 minutes following administration of Cyclosporine ophthalmic emulsion.

Use in Pregnancy:

There are no adequate and well-controlled studies of Cyclosporine Ophthalmic Emulsion in pregnant women. It should be administered to pregnant women if clearly needed.

Use in Lactating women:

Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of Cyclosporine Ophthalmic Emulsion, caution should be exercised when Cyclosporine is administered to a nursing woman.

Paediatric Use:

The safety and efficacy of Cyclosporine Ophthalmic Emulsion have not been established in paediatric patients below the age of 16. But clinical study shows that Cyclosporine Ophthalmic Emulsion is safe for children above one year of age.

Storage:

- Store between 15^o-25^oC.
- Don't use for longer than one month after first opening.
- Keep out of the reach of children.

Packing:

Cyporin Sterile Ophthalmic Emulsion : Each plastic dropper bottle contains 3 ml/5 ml/10 ml sterile ophthalmic emulsion.



Manufactured by:
ARISTOPHARMA LTD.
SHAMPUR-DHAKA-BANGLADESH

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