

# Cyporin

Cyclosporine 0.05% & 0.1%  
Ophthalmic Emulsion

## Composition:

**Cyporin 0.05% Ophthalmic Emulsion:** Each ml contains Cyclosporine USP 0.5 mg.

**Cyporin DS Ophthalmic Emulsion:** Each ml contains Cyclosporine USP 1 mg.

## Pharmacology:

Cyclosporine is a calcineurin inhibitor immunosuppressant agent when administered systemically. Cyclosporine has been shown to have an anti-inflammatory effect whereby it inhibits the production and/or release of pro-inflammatory cytokines. In patients with dry eye disease, topical administration of Cyclosporine is believed to exert an immunomodulatory effect.

## Indications:

**Cyporin 0.05% 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).

**Cyporin DS Ophthalmic Emulsion** is indicated to treatment of vernal keratoconjunctivitis (VKC) in children and adults & severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes.

## Dosage and Administration:

### Cyporin 0.05% Ophthalmic Emulsion:

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.

### Cyporin DS Ophthalmic Emulsion:

**In case of VKC:** Instill one drop 4 times daily (morning, noon, afternoon, and evening) in each affected eye(s).

**In case of Severe keratitis in adult patients with dry eye disease:** Instill one drop once daily to be applied to the affected eye(s) at bedtime. Response to treatment should be reassessed at least every 6 months.

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. If contact lenses are worn, they should be removed prior to the administration of this formulation and lenses may be reinserted in 15 minutes following administration of Cyclosporine ophthalmic emulsion.

## Overdose:

A topical overdose is not likely to occur after ocular administration. If overdose with Cyclosporine occurs, treatment should be symptomatic and supportive.

## Use in Special Group:

### Pregnancy Use:

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.

### Lactating Women Use:

Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated.

### Paediatric Use:

• The safety and efficacy of Cyclosporine 0.05% 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.

• The safety and efficacy of Cyclosporine 0.1% Ophthalmic Emulsion have not been established in paediatric patients below the age of 4 through 18 years of age.

## Storage:

- Store below 25°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

## Packing:

**Cyporin 0.05% Ophthalmic Emulsion:** Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

**Cyporin DS Ophthalmic Emulsion:** Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.