IMUDROPS Eye Drops (Cyclosporine 0.05%)

**Composition**

Each ml contains:
- Cyclosporine, USP ..............0.50 mg
- Aqueous buffered vehicle ..........q.s.

**Dosage Form**

Eye Drops

**Pharmacology**

- **Pharmacodynamics**

  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, cyclosporine emulsion is thought to act as a partial immunomodulator. The exact mechanism of action is not known.

- **Pharmacokinetics**

  Blood cyclosporine A concentrations were measured using a specific high pressure liquid chromatography-mass spectrometry assay. In all the samples collected, after topical administration of cyclosporine 0.05%, b.i.d., in humans for up to 12 months, blood concentrations of cyclosporine were below the quantitation limit of 0.1 ng/mL. There was no detectable drug accumulation in blood during 12 months of treatment with cyclosporine eye drops.

**Indications**

Cyclosporine eye drops are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

**Dosage And Administration**

Invert the unit dose vial a few times to obtain a uniform micro-emulsion before using. Instil one drop of cyclosporine eye drops twice a day in each eye, approximately 12 hours apart. Cyclosporine can be used concomitantly with artificial tears, allowing a 15-minute interval between the products. Discard the vial immediately after use.

**Contraindications**

Cyclosporine Eye drops are contraindicated in patients with active ocular infections and in patients with a known or
suspected hypersensitivity to any of the ingredients in the formulation.

**Warnings And Precautions**

- **Drug Interactions**
  Not applicable

- **Use in Renal and Hepatic Impairment**
  Not applicable

- **Potential for Eye Injury and Contamination**
  To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

- **Use with Contact Lenses**
  Cyclosporine ophthalmic micro 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 the emulsion. Lenses may be reinserted 15 minutes following administration of cyclosporine ophthalmic emulsion.

- **Pregnancy**
  **Pregnancy Category C**
  **Teratogenic Effects**

  Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% cyclosporine eye drops twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryo fetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 3,000 and 10,000 times greater (normalized to body surface area), respectively, than the daily human dose.

  Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 times greater than the daily human dose).

  There are no adequate and well-controlled studies of cyclosporine ophthalmic microemulsion in pregnant women. Cyclosporine ophthalmic micro emulsion should be administered to a pregnant woman only if clearly needed.

- **Lactation**
  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 eye drops, caution should be exercised when cyclosporine is administered to a nursing mother.

- **Paediatric Use**
  The safety and efficacy of cyclosporine eye drops have not been established in paediatric patients below the age of 16
years.

Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

Undesirable Effects

The most common adverse event following the use of cyclosporine was ocular burning (17%). Other events reported in 1-5% of patients included conjunctival hyperaemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging and visual disturbance (most often blurring).

Overdosage

No data available.

Incompatibility

Not applicable.

Shelf-Life

24 months

Storage And Handling Instructions

Store in a cool, dry and dark place.

Packaging Information

IMUDROPS Eye Drops.............3 x 5 single-use vials of 0.5 ml each

Information For Patients

The micro-emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes and the remaining contents should be discarded immediately after administration. Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. Cyclosporine 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 the emulsion. Lenses may be reinserted 15 minutes following administration of cyclosporine eye drops.

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