

**Ciclosporin 1mg/ml (Ikervis®) eye drops for use in ophthalmology for severe dry eye**

**Shared Care Protocol**

This protocol provides prescribing and monitoring guidance for ciclosporin topical ocular therapy. It should be read in conjunction with the Summary of Product Characteristics (SPC) available on [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) and the [BNF](#)

**Shared Care Protocol – Responsibilities**

Shared care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Unless otherwise stated in the protocol, the responsibilities are as follows:

**Specialist**

- Initiate treatment and prescribe until the dose is stable and/or the GP formally agrees to shared care
- Ensure the patients understand the nature and complications of drug therapy and their role in reporting adverse effects promptly
- Provide copy of patient information leaflet and drug monitoring card where appropriate
- Send a letter to the GP requesting shared care. Outline shared care protocol criteria
- Liaise with GP regarding changes in disease management, drug dose, missed clinic appointments
- Be available to give advice to GP and patient throughout treatment

**GP**

- Prescribe medication once the dose is stable or shared care is agreed
- Ensure all monitoring is completed in accordance to the specific shared care protocol.
- Check and record results then advise the specialist of any deteriorations or abnormal results
- Notify the specialist to any changes in patients condition, any adverse drug reactions or failure to attend tests

**Patient**

- Agree to treatment and monitoring after making an informed decision
- Agree to being under the shared care of the GP and specialist
- Attend for blood tests and monitoring when required
- Ensure monitoring card is kept up to date and is brought to all appointments
- Report any side effects to the GP or a member of the specialist team

### Background for Use

Ciclosporin 1mg/1ml eyedrops (Ikervis®) are recommended for use in the management of severe dry eye causing keratitis which does not respond to standard treatments e.g. tear substitutes, punctal plugs, punctal surgery or topical anti inflammatories. Ciclosporin has an anti-inflammatory effect on the cornea and lacrimal gland. Its use in the management of severe dry eye is supported by NICE TA 369 (Dec 2015).

### Supporting Information

#### Contraindications and Precautions

Contraindications-

- Hypersensitivity to the active substance or any of the excipients listed in the SPC.
- Active or suspected ocular/peri ocular infection.

Precautions-

- Use in caution in patients with ocular herpes.
- Contact lenses should be removed before instillation of drops at bedtime.
- Use in caution in patients with glaucoma as use of topical beta blockers has been shown to reduce tear production.
- Co-administration of ciclosporin with eye drops containing corticosteroids may potentiate the effects of topical ciclosporin on the immune system.

Pregnancy-

Not recommended for use in women of childbearing potential not using effective contraception. Not recommended for use in pregnancy unless the potential benefit to the mother outweighs the potential risk to the foetus.

Breastfeeding-

Following oral administration, ciclosporin is excreted in breast milk. There is insufficient information on the effects of ciclosporin in newborns/infants. However, at therapeutic doses of ciclosporin in eye drops, it is unlikely that sufficient amounts would be present in breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from IKERVIS therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

#### Dosage

##### **Must be initiated by an ophthalmologist in secondary care.**

Adults: One drop to the affected eye (s) at bedtime. Response to treatment should be reviewed every 6 months. Close the eyelid for 2 minutes after instillation to promote local activity and limit systemic absorption.

Paediatrics: The use of ciclosporin eyedrops in dry eye conditions has not been investigated in patients < 18 years.

#### Time to Response

Manufacturer states that treatment should be reviewed every 6 months however patients will be reviewed by secondary care ophthalmologist 3 months after starting treatment. If no response is seen at this time, treatment will be discontinued. Patients who demonstrate response to treatment will continue with ciclosporin but remain under regular review with Oxford eye hospital. GPs would be asked to provide repeat prescriptions for treatment but would not be responsible for stopping/reviewing treatment.

**Pre-Treatment Assessment**

N/A

**Ongoing Monitoring**

N/A

**Actions to be taken**

N/A

**Notable Drug Interactions (Refer to BNF and SPC)**

Topical steroids :Co-administration of ciclosporin eyedrops with eye drops containing corticosteroids could potentiate the effects of ciclosporin on the immune system

Topical beta blockers: There is limited experience with ciclosporin eyedrops in the treatment of patients with glaucoma. Caution should be exercised when treating these patients concomitantly with ciclosporin eyedrops, especially with beta-blockers which are known to decrease tear secretion

**Back-up Information and Advice**

It is envisaged that GPs will be responsible for providing a continued supply for those patients who continue to benefit from treatment. These patients will remain under the care of the Oxford Eye Hospital in addition for regular review by the corneal team.

**Contact numbers**

Person	Contact Number
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**References**

1. EMC <https://www.medicines.org.uk/emc/medicine/30584> for Ikervis® [accessed 18/05/2016]
2. Ciclosporin for treatment dry eye disease that has no improved despite treatment with artificial tears. NICE technology appraisal guidance TA369 <https://www.nice.org.uk/guidance/ta369/chapter/3-The-companys-submission> [accessed 18/05/2016]