Ciclosporin 0.1% eye drops (IKERVIS®) INFORMATION FOR PRIMARY CARE



RAG List Status

Ciclosporin 0.1% eye drops (IKERVIS[®]) is classified as a GREEN+ drug (following specialist initiation) drug by the County Durham & Darlington Area Prescribing Committee.

Indication

Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.

What is it?

Ciclosporin (in 1mg/mL eye drop formulation) has an anti inflammatory effect on the cornea and the lacrimal (tear) gland. Following administration, ciclosporin blocks the expression of pro inflammatory cytokines and subsequently enters corneal and conjunctival infiltrated T cells, activating them.

NICE Guidance

<u>NICE TA369</u>: Ciclosporin is recommended as an option, within its marketing authorisation, for treating severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes. NICE expects the number of patients to require treatment with IKERVIS® to be up to 81per 100,000 population.

When should GPs be asked to prescribe?

GP will only prescribe when treatment has been initiated by a consultant ophthalmologist and the patient meets the NICE TA criteria.

Dosage and Administration

One drop at bedtime in each eye.

Dose Modifications

None required.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed (refer to SPC).
- Pregnancy and breast feeding.
- Active or suspected ocular or peri-ocular infection.
- Ciclosporin is not recommended in women of childbearing potential not using effective contraception.

Cautions

- Co-administration of with eye drops containing corticosteroids could potentiate the effects of ciclosporin on the immune system ,
- Patients with a history of ocular herpes.
- Patients with glaucoma, especially with beta blocker treatment as these are known to reduce tear secretion.
- Patients wearing contact lenses have not been studied. Careful monitoring of patients with severe keratitis is recommended. Contact lenses should be removed before instillation of the eye drops at bedtime and may be reinserted at wake-up time.
- IKERVIS[®] contains cetalkonium chloride which may cause eye irritation.

Drug Interactions

- No interaction studies have been performed with IKERVIS.
- Co-administration of IKERVIS with eye drops containing corticosteroids could potentiate the effects of ciclosporin on the immune system caution is advised.

Adverse Effects

The most common adverse reactions with ciclosporin are eye pain, eye irritation, lacrimation, ocular hyperaemia and eyelid erythema.

This medicinal product may induce temporary blurred vision or other visual disturbances which may affect the ability to drive or use machines. Patients should be advised not to drive or use machines until their vision has cleared.

Monitoring

GP reviewed to ensure treatment to check for side-effects and to ensure treatment is still effective at least every 6 months.

References

SPC: IKERVIS 1 mg/mL eye drops. Last Updated on eMC 21-Jul-2015. Santen UK Limited.