Ikervis® Information Sheet for Primary Care Prescribers

Licensed Indications
Severe keratitis that has not improved despite treatment with tear substitutes (NICE TA369).

Therapeutic Summary
Approved by NICE TA369. The Tear Film & Ocular Surface Society (TFOS) DEWS II report redefine dry eyes as: *"…a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles*."

Ciclosporin has an anti-inflammatory effect on the cornea and the lacrimal gland. Following administration, ciclosporin blocks the expression of pro-inflammatory cytokines and subsequently enters corneal and conjunctival infiltrated T-cells, activating them.

Medicines Initiation
Amber: Specialist initiated, Primary Care to continue (no shared care guidelines). Ikervis® is suitable for prescribing in primary care following specialist initialisation once the patient has been stabilised on treatment. The recommending Opthalmologist must send an information sheet with indication for use and likely duration of treatment. This information sheet is supporting material for those responsible for continuing supply in primary care.

Dose Regimen
- One drop daily at bed time to the affected eye(s).
- If a dose is missed, treatment should be continued on the next day as normal.

Administration Advice
- Patients should be advised not to instil more than one drop in the affected eye(s).
- Prior to administration, the single-dose container should be gently shaken.
- Patients should be instructed to use nasolacrimal occlusion and to close the eyelids for 2 minutes after instillation, to reduce the systemic absorption. This may result in a decrease in systemic undesirable effects and an increase in local activity.
- If more than one topical ophthalmic product is being used, these must be administered at least 15 minutes apart. Ikervis® should be administered last.

Products available
Ikervis® - Ciclosporin 1mg/ml eye drops [emulsion] (30x0.3ml single dose, single-use containers, £72.00). Each dose container is sufficient to treat both eyes, any unused emulsion should be discarded immediately.

Duration of treatment
Treatment with ciclosporin is long term – where a specific course length is required this should be communicated in the GP letter.

Patient response to treatment should be assessed at least every 6 months by the eye specialist in secondary care. Ensure that repeat prescriptions will guarantee continuation of treatment until review.

Contraindications
Hypersensitivity to the active substance or to any of the excipients. Active or suspected ocular or peri-ocular infection. If patient develops an eye infection withhold ciclosporin treatment and refer to specialist immediately for treatment.

Precautions
- Contact lens wear should be avoided unless under specialist advice. If the eye drops are being instilled once daily at bedtime, the contact lenses should be removed before instillation of the eye drops and may be reinserted after waking up the next morning.
- Wash hands after use.
- Do not use in pregnancy
- Concomitant therapy:
    - There is limited experience with ciclosporin in the treatment of patients with glaucoma. Regular clinical monitoring should be exercised when treating these patients concomitantly with Ikervis®, especially with beta-blockers which are known to decrease tear secretion.

Monitoring
No specific monitoring of patients is required as systemic absorption is minimal.

Adverse Effects
Common adverse reactions include eye pain (19%), eye irritation (17.5%), ocular hyperaemia (5.5%), increased lacrimation (4.9%), and eyelid erythema (1.7%) which were usually transitory and occurred during instillation.

Explicit criteria for review and discontinuation of the medicine
Review/discontinuation of therapy should only be carried out by the corneal/external eye disease specialist in secondary care.

Clinically relevant medicine interactions and their management
No interaction studies have been performed with Ikervis®. Co-administration of ciclosporin with eye drops containing corticosteroids could potentiate the effects of ciclosporin on the immune system.

For further information on contraindications, precautions, adverse effects and interactions refer to the BNF or Summary of Product Characteristics.

Information given to patient (*see also Administration Advice)*
- Mild irritation in the first few days of treatment may occur.
- Wash hands before and after use.
- Medication should be stored below 25˚C, unused contents of each container should be discarded immediately.
- After opening the aluminium pouches the single-dose containers should be kept in the pouch in order to protect from light and avoid evaporation (one pouch contains five single-dose containers).

The company Patient Information Leaflet (PIL) for Ikervis® eye drops can be found here.

REFERENCES

1. Tear and Film Ocular Surface Society, Report of the International Dry Eye Workshop II (TFOS DEWS II Report) (published July 2017). Accessed online: https://tfosdewsreport.org/report-pathophysiology/106_36/en/#A119 [accessed 10 September 2020]

2. IKERVIS 1 mg/mL eye drops, emulsion (Santen UK Limited). Summary of Product Characteristics (last revised 16 March 2020). Accessed online: https://www.medicines.org.uk/emc/product/6937 [accessed 28 July 2020].

3. NICE TA 369: Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears (published 16 December 2015). Accessed online: https://www.nice.org.uk/guidance/ta369 [accessed 19 August 2020]

4. Nottinghamshire Area Prescribing Committee *Ciclosporin Eye Drops (Ikervis®) Information sheet for Primary Care Prescribers 2016 – adapted from North Central London Joint Formulary Committee; Ciclosporin eye preparations fact sheet – treatment of ocular inflammatory conditions, October 2015*

DOCUMENT CONTROL

Document ratification and history	
Produced by:	WEL CCGs Medicines Optimisation Team, with input from Dr P. Georgoudis, Barts Health NHS Trust Ophthalmology Lead for Dry Eyes *Adapted with kind permission from the Nottinghamshire Area Prescribing Committee Ciclosporin Eye Drops (Ikervis®) Information sheet for Primary Care Prescribers*
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