Ciclosporin Eye Drops (Ikervis®)

Traffic Light Classification – AMBER 2

Information sheet for Primary Care Prescribers

Optum in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Licensed Indications

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

Therapeutic Summary

Approved by NICE TA369. Dry eye disease may be considered to have an inflammatory immunological mechanism. Ciclosporin has been shown to have an anti-inflammatory effect. Following ocular administration, ciclosporin is passively absorbed into T-lymphocyte infiltrates in the cornea and conjunctiva and inactivated calcineurin phosphatase. Ciclosporin-induced inactivation of calcineurin inhibits the dephosphorylation of the transcription factor NF-AT and prevents NF-AT translocation into the nucleus, thus blocking the release of pro-inflammatory cytokines such as IL-2.

Medicines Initiation

AMBER 2 – medication is suitable for prescribing in primary care following specialist initialisation once the patient has been stabilised on treatment. Opthalmologist must send information sheet with indication for use and likely duration of treatment. This is a supporting material for those responsible for continuing supply in primary care.

Dose Regimen

Once daily at bed time to the affected eyes.

Products available

Ikervis® - Ciclosporin 1mg/ml eye drops [emulsion] (30x0.3ml single dose, single-use containers, £72.00, MIMS September 2018). 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 will be reviewed 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
- Breast feeding. 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 benefits of breast feeding for the child and the benefit of therapy for the woman.

Monitoring

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

Adverse Effects

Common adverse reactions include eye pain (19.2%), eye irritation (17.8%), lacrimation (6.4%), ocular hyperaemia (5.5%) 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 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

- Mild irritation in the first few days of treatment may occur.
- May induce temporary blurred vision or other visual disturbances, which may affect the ability to drive or use machines. If this occurs the patient should be advised not to drive or use machines until their vision has cleared.
- 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).

PIL for Ikervis® eye drops can be found here.

REFERENCES

Ciclosporin SPC, accessed 25/9/18 http://www.medicines.org.uk/emc/medicine/30584

NICE TA 369 – Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears

North Central London Joint Formulary Committee; Ciclosporin eye preparations fact sheet – treatment of ocular inflammatory conditions, October 2015

Nottinghamshire Joint Formulary . Ciclosporin Drops Ikervis – Information sheet for primary care prescribers .

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