SEVERE KERATITIS WITH DRY EYE DISEASE

Severe keratitis is an inflammation of the cornea, which can result from dry eye disease. It is a distressing condition for patients and has a very significant impact on their well being and quality of life, and corneal inflammation, if left untreated, can lead to further complications, such as permanent scarring and infections.

IKERVIS FOR THE TREATMENT OF SEVERE KERATITIS IN ADULTS WITH DRY EYE DISEASE

Ikervis is a topical preparation of ciclosporin licensed in the UK, and was given approval for use in the NHS by the SMC in October 2015 and NICE in December 2015 for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. Ikervis has been shown to reduce ocular surface inflammation and reduces corneal damage, consistent with an improvement in patients’ disease severity.\(^1\) Ikervis is initiated by ophthalmologists; treatment should be started as soon as possible and a specialist should make an assessment of the patient’s response to treatment within 6 months. Ikervis should be continued to be prescribed during this period. Severe keratitis is a chronic condition that takes time to treat and it is therefore important that the patient continues with this treatment even if they do not feel an improvement of the symptoms in the first weeks or months.

USE OF IKERVIS

Patients should follow these instructions when taking Ikervis:

- The daily dose is one drop per affected eye, once daily before the patient goes to sleep.
- Patients should remove their contact lenses before using the drops.
- Ikervis is provided in single use containers. Each single-dose container is sufficient to treat both eyes. Prior to administration, the container should be gently shaken. Any unused product should be discarded immediately.
- If more than one topical ophthalmic medicinal product is being used, they must be administered at least 15 minutes apart. Ikervis should be administered last.
- Patient should be instructed to press a finger into the corner of the eye by the nose and close the eyelids for 2 minutes after administration to reduce the systemic absorption. This may result in a decrease in systemic undesirable effects and an increase in local activity.

- Shortly after application, the patient may experience a transient stinging sensation. No special monitoring is required.

Please refer to the prescribing information for further information and the summary of product characteristics can be found at: www.medicines.org.uk/EMC/medicine/30584

Ikervis must not be used in patients who have, or are suspected to have, an infection of the eye or the tissues around the eye. For the full list of restrictions, please refer to the prescribing information.

POSSIBLE SIDE EFFECTS

The most common side effects with Ikervis (which may affect more than 1 in 10 people) are pain and irritation in the eye; other common side effects are lacrimation [excessive tears], ocular hyperaemia [red eye], and erythema [redness] of the eyelid. These symptoms are usually short lasting and occur at the time the eye drops are used. For the full list of all side effects reported with Ikervis please refer to the prescribing information.

If you have any questions or concerns please contact your local ophthalmologist.

### Abbreviated Prescribing Information

Please refer to the product Summary of Product Characteristics for full details.

**Product Name:** Ikervis 1 mg/mL eye drops, emulsion.

**Composition:** One ml of emulsion contains 1 mg of ciclosporin and 0.05mg cetalkonium chloride as an excipient. Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients.

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

**Dosage and administration:** Ikervis treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. The recommended dose is one drop of Ikervis once daily to be applied to the affected eye(s) at bedtime. Response to treatment should be reassessed at least every 6 months. To reduce systemic absorption, advise patients to use nasolacrimal occlusion and to close the eyelids for 2 minutes after instillation. If more than one topical ophthalmic product is used, 15 minutes should separate their administration. Ikervis should be administered last.

**Contraindications:** Hypersensitivity to any of the ingredients. Active or suspected ocular or peri-ocular infection.

**Warnings and Precautions:** Use with caution in patients with a history of ocular herpes. Contact lenses: Patients wearing contact lenses have not been studied. Monitor carefully inpatients with severe keratitis. Contact lenses should be removed before instillation of the eye drops at bedtime and may be reinserted at wake-up time. Concomitant therapy: Use with caution in patients with glaucoma, especially in those receiving concomitant beta-blockers which are known to decrease tear secretion. Immune system effects: Medicinal products which affect the immune system, including ciclosporin, may affect host defences against infections and malignancies. Contains cetalkonium chloride which may cause eye irritation.

**Interactions with other medicinal products:** Coadministration with eye-drops containing corticosteroids may potentiate effects on the immune system.

**Pregnancy and Breast Feeding:** Not recommended in women of childbearing potential not using effective contraception or during pregnancy unless the potential benefit to the mother outweighs the potential risk to the foetus. Benefits of treatment must be weighed against the benefits of breast feeding.

**Driving and using machines:** Moderate influence on the ability to drive and use machines. If blurred vision occurs on instillation, the patient should be advised to not drive or use machines until their vision has cleared.

**Undesirable Effects:** Consult SmPC for full details. The most common adverse reactions in clinical studies were eye pain, eye irritation, lacrimation, ocular hyperaemia and eyelid erythema. Patients receiving immunosuppressive therapies including ciclosporin, are at an increased risk of infections.

**Special Precautions for Storage:** Do not freeze. After opening of the aluminium pouches, the single-dose containers should be kept in the pouches in order to protect from light and avoid evaporation. Discard any opened individual single-dose container with any remaining emulsion immediately after use.

**Package quantities and basic NHS cost:** 30 x 0.3ml single-dose containers £72.00.

**Product Licence Holder:** Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland (PL 16058/0012) [EU/1/15/990/001 & 002]

**Date of Authorisation:** March 2015

**Legal Category:** POM

**Date of last revision of Prescribing Information:** 14/04/2016

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Santen UK Limited (Email medinfo@santen.co.uk or telephone: 0345 075 4863).