IKERVIS® (ciclosporin 1 mg/mL)

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

Product Name: IKERVIS® 1 mg/ml(ciclosporin) 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.** The recommended dose is one drop once daily to be applied to the affected eye(s) at bedtime. Ikervis treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. Response to treatment should be reassessed at least every 6 months **Contraindications:** Hypersensitivity to any of the ingredients. Ocular or peri-ocular malignancies or premalignant conditions. Active or suspected ocular or peri-ocular infection. **Warnings and Precautions:** Use with caution in patients with a history of ocular herpes and contact herpes. Use with caution in patients with a concomitant therapy with beta-blockers, corticosteroids and IKERVIS®. Regular examination of the eye(s) is recommended, e.g. at least every 6 months, when IKERVIS is used for years. Consult SmPC for full details. **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. 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 **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:** Very common adverse reactions in clinical studies or during post-marketing experience are eye pain (19%) and eye irritation (17.5%). Other common adverse reactions observed were eyelid erythema, lacrimation, ocular hyperaemia, vision blurred, eyelid oedema, conjunctiva! hyperaemia, and eye pruritus. Patients receiving immunosuppressive therapies including ciclosporin are at increased risk of infections. Consult SmPC for full details **Package quantities and basic NHS cost:** 30 x 0.3ml single-dose containers £72.00. **Marketing Authorisation Holder:** Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland (PLGB16058/0027;EU/1/15/990/001) **Legal Category:** POM IKERVIS®is a registered trademark of Santen Pharmaceutical Co., Ltd. **Job code:** NP-IKERVI-UK-0072 **Date of Preparation:** February 2022

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Santen UK Limited (Email medinfo@santen.co.uk or telephone: 0345 075 4863).

Deliver sustained relief from dry eye disease with ikervis®
1mg/ml ciclosporin eye drops, emulsion

VERKAZIA® 1 mg/mL eye drops, emulsion (ciclosporin)

VERKAZIA® 1 mg/mL eye drops, emulsion (ciclosporin)

ABBREVIATED PRESCRIBING INFORMATION. Please refer to the Summary of Product Characteristics (SmPC) for full details.

Composition: One mL of emulsion contains 1 mg ciclosporin and 0.05 mg cetalkonium chloride as an excipient. For full list of excipients please refer to SmPC.
Indication: Treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.
Dosage and administration: Verkazia treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. The recommended dose is one drop of Verkazia 4 times a day to be applied to each affected eye during the VKC season. If signs and symptoms persist after the end of the season, treatment can be maintained at the recommended dose or decreased to 1 drop twice daily once adequate control is achieved.
Contraindications: Hypersensitivity to any of the ingredients Ocular or peri-ocular malignancies or premalignant conditions. Active or suspected ocular or periocular infection.
Warnings and Precautions: Use with contact lenses not recommended. Verkazia should be used with caution in patients with an active orofacial herpes simplex infection, a history of ocular herpes, varicella-zoster or vaccinia virus infection and concomitant corticosteroid use. Efficacy and safety of Verkazia have not been studied beyond 12 months. Therefore, regular examination of the eye(s) is recommended, e.g. every 3 to 6 months, when Verkazia is used for more than 12 months
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. 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 Verkazia therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Driving and using machines: Verkazia has moderate influence on the ability to drive and use machines.
Undesirable effects: Consult SmPC for full details. The most common adverse reactions seen in clinical trials with Verkazia were eye pain (11%) and eye pruritus (9%) which were usually transitory and occurred during instillation. Other common adverse reactions observed were upper respiratory tract infection, headache, ocular hyperaemia, eye irritation, ocular discomfort, foreign body sensation in eyes, lacrimation increased, vision blurred, erythema of eyelid, eyelid oedema, and cough.
Package Quantities and Cost: One pouch contains 5 single dose containers. Pack size 120 single dose containers £288.00.
Legal Category: Product subject to medicinal prescription.
Marketing Authorisation numbers: PLGB 16058/0028, EU/1/17/1219/004
Marketing Authorisation Holder: SANTEN Oy, Niittyhaankatu 20, 33720 Tampere, Finland.
VERKAZIA® is a registered trademark of Santen Pharmaceutical Co., Ltd.
Job No: NP-VKC-UK-0079
Date of Prescribing Information: February 2022

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Santen UK Limited email: medinfo@santen.co.uk or telephone: 0345 075 4863.

Santen logo etc. and Verkazia is a registered trademark of Santen Pharmaceutical Co., Ltd.

Verkazia®
1 mg/ml ciclosporin eye drops, emulsion
See VKC in a different light

▼ This medicinal product is subject to additional monitoring.

Product Name: ROCLANDA® 50 µg/mL + 200 µg/mL eye drops, solution (latanoprost and netarsudil)

Abbreviated Prescribing Information

Composition: One mL of solution contains 50 µg of latanoprost and 200 µg of netarsudil (as mesylate).One mL of solution contains 200 µg of benzalkonium chloride. Please reffer to the Summary of Product Characteristsics (SmPC) for a full list if excipients.
Indication: Reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction
Dosage and administration: Treatment should be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. The recommended dose is one drop in the affected eye(s) once daily in the evening. Contact lenses should be removed prior to instillation of ROCLANDA® and may be reinserted 15 min following its administration. Concomitant topical ophthalmic therapy: each medicinal product should be administered at least 5 min apart. Other eye drops should be administered before ROCLANDA®. Eye ointments should be administered last. To reduce systemic absoption the compression of the lachrymal sac at the medial canthus for 1 min is recommended. The tip of the dispensing container should avoid contacting the eye, surrounding structures, fingers, or any other surface in order to avoid contamination.
Contraindications: Hypersensitivity to the active substance(s) or to any of the excipients.
Warnings / Precautions: Iris pigmentation: latanoprost may gradually change eye colour. Patients should be informed of possibility of a permanent change in eye colour. Herpetic keratitis condition: latanoprost should be used cautiously in patients with a history of herpetic keratitis, and should be avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues. Macular oedema risk: latanoprost should be used with caution in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema. Iritis/uveitis risk: latanoprost can be used with caution. Asthma exacerbation: asthmatic patients should be treated with caution. Periorbital skin discolouration: non-permanent periorbital skin discolouration has been observed on treatment with latanoprost. Eyelash changes: reversible changes of eyelashes and vellus hair in the treated eye and surrounding areas may exist. Benzalkonium chloride content: ROCLANDA® contains benzalkonium chloride which may cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface and is known to discolour soft contact lenses. It should be used with caution in dry eye patients and in patients where the cornea may be compromised.
Interaction with other medicinal products: the use of two or more prostaglandins, prostaglandin analogues or prostaglandin derivatives is not recommended.
Pregnancy and breastfeeding: ROCLANDA® should not be used during pregnancy.
Effects on ability to drive and use machines: If transient blurred vision occurs at instillation, the patient should wait until the vision clears before driving or using machines.
Undesirable effects: *Very common:* conjunctival hyperaemia, cornea verticillata, instillation site pain, iris hyperpigmentation, eyelash and vellus hair changes of the eyelid. *Common:* conjunctival haemorrhage, vision blurred, lacrimation increased, erythema of eyelid, eye pruritus, eye irritation, visual acuity reduced, eyelid oedema, punctate keratitis, corneal disorder, conjunctival oedema, conjunctivitis allergic, eye pain, dry eye, foreign body sensation in eye, eyelid margin crusting, blepharitis, instillation site erythema, instillation site discomfort, vital dye staining cornea present, dermatitis contact. *Uncommon:* photophobia. Refer to SmPC for full list of side effects.
Special precautions for storage: Store in a refrigerator (2 °C – 8 °C) before opening. Store in the original carton in order to protect from light. Opened bottle: Throw away 4 weeks after first opening the bottle. Do not store above 25 °C.
MA Holder: Santen Oy, 33720 Tampere, Finland.
MA number: PLGB 16058/0034
Package quantities and basic NHS cost: Roclanda is supplied in clear low density polyethylene bottles (2.5 ml fill in a 4 ml container), opaque white low density polyethylene tips with opaque white polypropylene screw caps and anti-tamper seals. Carton containing 1 bottle. Price: £14.00
Legal Category: POM
Date of Prescribing Information: April 2023
Prescribing Information No: NP-ROC-UK-0010

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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).

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