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: Treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. The recommended dose is one drop 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. 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. *Contact lenses:* Patients wearing contact lenses have not been studied. Monitor carefully in patients 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. Caution should be exercised with the co-administration of corticosteroids and IKERVIS since the concomitant use of corticosteroids may potentiate the effects of IKERVIS on the immune system. *Immune system effects:* Ophthalmic medicinal products which affect the immune system, including ciclosporin, may affect host defences against local infections and malignancies. Regular examination of the eye(s) is recommended at least every 6 months, when IKERVIS is used for years. Contains cetalkonium chloride which may cause eye irritation. Patients should be monitored in case of prolonged use.

Interactions with other medicinal products: Co-administration 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. Very common adverse reactions in clinical studies or during post-marketing experience are eye pain and eye irritation. Other common adverse reactions observed were eyelid erythema, lacrimation, ocular hyperaemia, vision blurred, eyelid oedema, conjunctival hyperaemia, and eye pruritus. Patients receiving immunosuppressive therapies including ciclosporin are at increased risk of infections.

Package quantities: 30 x 0.3ml single- dose containers.

Product Licence Holder: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland (EU/1/15/990/001)

Legal Category: Product subject to medicinal prescription.

IKERVIS® is a registered trademark of Santen Pharmaceutical Co., Ltd.

Job code: NP-IKERVI-IE-0030

Date of preparation: January 2022

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie . Adverse events should also be reported to Santen UK Limited (email medinfo@ santen.co.uk or telephone: +353 1 695 0008).

Santen

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Medical Practitioner Certification	Sanjay Patel Indigomedical Medical Practitioner 31-Jan-2022 13:00:52 GMT+0000

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▼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 refer 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 and 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.

Package quantities: Roclanda is a clear, liquid eye drop solution in a plastic bottle. Each bottle contains 2.5 ml of the medicine and each pack contains 1 bottle with a screw-cap.

Product licenceholder: Santen Oy, 33720 Tampere, Finland (EU/1/20/1502/001)

Legal Category: Product subject to medicinal prescription.

Date of Prescribing Information: November 2023
Job Code Number : NP-ROC-IE-0005

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie . Adverse events should also be reported to Santen UK Limited (email medinfo@ santen.co.uk or telephone: +353 1 695 0008).

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Medical Practitioner Certification	Sanjay Patel Indigomedical Medical Practitioner 08-Nov-2023 11:41:08 GMT+0000

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