COSOPT® Preservative-Free (20 mg/mL dorzolamide + 5 mg/mL timolol)

Product Name: COSOPT® Preservative-Free 20 mg/ml + 5 mg/ ml, eye drops, solution, single-dose container. COSOPT® iMulti 20 mg/ml + 5 mg/ml eye drops, solution.

Composition: Each millilitre contains 20 mg dorzolamide (22.26 mg dorzolamide hydrochloride) and 5 mg timolol (6.83 mg timolol maleate). Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients.

Indication: Treatment of elevated intra-ocular pressure (IOP) in patients with open-angle glaucoma, or pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.

Posology and Method of Administration: One drop of COSOPT in the conjunctival sac of the affected eye(s), two times daily. If another topical ophthalmic agent is being used, administer COSOPT and the other agent at least ten minutes apart. COSOPT is a sterile solution that does not contain preservative. Safety in paediatric patients less than 2 years of age has not been established. Please see the SmPC for use in children of more than 2 years.

Contraindications: Hypersensitivity to any component of this medicine, reactive airway disease, including bronchial asthma, or a history of bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, sick sinus syndrome, sino-atrial block, second or third-degree atrioventricular block not controlled with pacemaker, overt cardiac failure, cardiogenic shock, severe renal impairment (CrCl <30 ml/min) or hyperchloraemic acidosis.

Warnings and Precautions: The same types of adverse reactions found with systemic administration of beta-blockers or sulphonamides may occur, these include severe reactions seen with sulphonamides such as Stevens-Johnson syndrome and toxic epidermal necrolysis. In patients with cardiovascular diseases (e.g. coronary heart disease, Prinzmetal's angina and cardiac failure) and hypotension, therapy with betablockers should be critically assessed and therapy with other active substances should be considered. Patients should be watched for signs of deterioration and adverse reactions. Betablockers should only be given with caution to patients with first degree heart block. Patients with severe peripheral circulatory disturbance/disorders (i.e. severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution. Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following administration of some ophthalmic beta-blockers. Use with caution, in patients with mild/moderate chronic obstructive pulmonary disease (COPD) and only if the potential benefit outweighs the potential risk. Use with caution in patients with hepatic impairment. Concomitant use of dorzolamide with oral carbonic anhydrase inhibitors is not recommended. Use of two topical beta-adrenergic blocking agents is not recommended. Caution in patients subject to spontaneous hypoglycaemia or with labile diabetes. These signs and symptoms of acute hypoglycaemia and hyperthyroidism may be masked. Caution in patients with corneal diseases. The anaesthetist should be informed when a patient is receiving timolol as beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline. Though no acid-base disturbances have been observed with COSOPT (preserved formulation), patients with a prior history of renal calculi may be at increased risk of urolithiasis. Patients with acute angle-closure glaucoma require therapeutic interventions in addition to ocular hypotensive agents. This medicinal product has not been studied with acute angle-closure glaucoma. Corneal oedema and irreversible corneal decompensation have been reported in patients with pre-existing chronic corneal defects and/or a history of intraocular surgery while using dorzolamide. Precautions should be used when prescribing in these groups of patients. Patients with a history of contact hypersensitivity to silver should not use COSOPT iMulti as dispensed drops may contain traces of silver from the container. This medicinal product has not been studied in patients wearing contact lenses. There is limited experience with COSOPT in infants and children. Please refer to the SmPC.

Interactions with Other Medicinal Products: There is a potential for additive effects resulting in hypotension and / or marked bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, catecholamine-depleting drugs or beta adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics, quanethidine, narcotics and monoamine-oxidase (MAO) inhibitors. Potentiated systemic beta-blockade (e.g. decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g. quinidine, fluoxetine, paroxetine) and timolol. Mydriasis resulting from concomitant use of ophthalmic beta-blockers and adrenaline (epinephrine) has been reported occasionally.

Pregnancy and Breast Feeding: Do not use in pregnancy or during breast-feeding.

Driving and using machines: Possible side effects such as blurred vision may affect some patients' ability to drive and/or operate machinery.

Undesirable Effects: (Refer to SmPC for complete information on side effects). The side effects observed with COSOPT or one of its components include: headache, depression, hallucination, burning and stinging, foreign body sensation in eye, conjunctival injection, blurred vision, corneal erosion, ocular itching, tearing, eyelid inflammation, eyelid irritation, iridocyclitis, signs and symptoms of ocular irritation including blepharitis, keratitis, decreased corneal sensitivity and dry eyes and visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases), ptosis, bradycardia, syncope, sinusitis, dyspnoea, dysgeusia, nausea and dyspepsia,

urolithiasis, signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, anaphylaxis, asthenia/fatigue, hypoglycaemia, cardiac arrest, heart block, AV block, cardiac failure, chest pain, palpitation, oedema.

Overdose: Treatment should be symptomatic and supportive. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Special Precautions for storage: Do not store above 25°C.

Price: COSOPT Preservative-Free 60 x 0.2mL single-dose containers £28.59; COSOPT iMulti 1 x 10ml bottle (60 days treatment) £28.00.

MA Holder: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland.

MA Numbers: COSOPT Preservative-Free PL 16058/0015 COSOPT iMulti PL 16058/0025

Legal Category: POM

Date of Prescribing Information: February 2020.

Job Code: NP-CSPTPF-UK-0016

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

Cosopt® Preservative-Free

(20 mg/ml dorzolamide + 5 mg/ml timolol eye drops)

DUCRESSA® (levofloxacin 5 mg per mL + dexamethasone 1 mg per mL)

DUCRESSA 1 mg/ml + 5 mg/ml, eye drops, solution

Abbreviated Prescribing Information

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

Product Name: Ducressa 1 mg/ml + 5 mg/ml, eye drops, solution

Composition: One ml of eye drops, solution, contains dexamethasone sodium phosphate equivalent to 1 mg of dexamethasone and levofloxacin hemihydrate equivalent to 5 mg of levofloxacin.One drop (about 30 microliter) contains about 0.03 mg of dexamethasone and 0.150 mg of levofloxacin. Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients.

Indication: Ducressa eye drops solution is indicated for prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults

Dosage and administration: Treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology. One drop instilled into the conjunctival sac after surgery every 6 hours. Duration of treatment is 7 days. Care should be taken not to discontinue therapy prematurely.

Contraindications: Hypersensitivity to any of the ingredients; viral disease of the cornea and conjunctiva; mycobacterial infections of the eye; fungal diseases of ocular structures; Untreated purulent infection of the eye.

Warnings and Precautions: Ducressa is for ocular use only. Ducressa must not be injected sub-conjunctively. The solution should not be introduced directly into the anterior chamber of the eye. Use with caution in patients with a history of hypersensitivity to quinolones and/or steroids. Tendon inflammation, Cushing's syndrome and/or adrenal suppression, After cataract surgery patients should not wear contact lenses for the whole duration of therapy with Ducressa.

Interactions with other medicinal products: The concomitant use of probenecid, cimetidine, or ciclosporin with levofloxacin altered some pharmacokinetic parameters of levofloxacin. Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems. CYP3A4 inhibitors may decrease dexamethasone clearance resulting in increased effects.

Pregnancy and Breast Feeding: Not recommended during pregnancy. Corticosteroids cross the placenta. Systemic corticosteroids and levofloxacin are excreted into human milk and may impair male and female fertility. No data are available, to indicate whether same effects occurs after ocular use.

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. Adverse reactions in clinical studies or during post-marketing experience are: *Very common* are Increase of the intraocular pressure; *Common*- Ocular burning, decreased vision and mucous strand. Discomfort*, irritation*, burning*, stinging*, itching* and blurred vision. *Uncommon*- Headache, dysgeusia, Eye irritation, abnormal sensation in eye, ocular hypertension, Pruritus, Headache, Lid matting, chemosis, conjunctival papillary reaction, lid oedema, ocular discomfort, ocular itching, ocular pain, conjunctival hyperaemia, conjunctival follicles, ocular dryness, lid erythema, and photophobia, Rhinitis, Allergic and hypersensitivity reactions, delayed wound healing, posterior capsular cataract*, opportunistic infections, glaucoma. *Rare and very rare*- Extra-ocular allergic reactions, including skin rash, Anaphylaxis, Laryngeal oedema, Conjunctivitis, mydriasis, ptosis, corticosteroid-induced uveitis, corneal calcifications, crystalline keratopathy, changes in corneal thickness*, corneal oedema, corneal ulceration and corneal perforation, Face oedema.

Package quantities and basic NHS cost: 1 bottle x 5 ml £8.30

Product Licence Holder: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland (PL 16058/0031)

Legal Category: Product subject to medicinal prescription.

Job code: NP-DUC-UK-0002
Date of preparation: April 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).

DUCRESSA®

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).

TAPTIQOM® (15 mcg/mL tafluprost + 5 mg/mL timolol)

Abbreviated Prescribing Information

Product Name: TAPTIQOM® tafluprost 15 micrograms/ml + timolol maleate 5 mg/ml eye drops, solution in single-dose container.
Composition: One drop (about 30 µl) contains about 0.45 micrograms of tafluprost and 0.15 mg of timolol. One single-dose container (0.3 ml) of eye drops contains 4.5 micrograms of tafluprost and 1.5 mg of timolol. Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients.
Indication: Reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative free eye drops.
Posology and method of administration: Recommended dose is one drop in the conjunctival sac of the affected eye(s) once daily. Not to exceed one drop per day in the affected eye. Not recommended in children or adolescents below the age of 18 years. In renal or hepatic impairment use with caution. To reduce systemic absorption, patients should be advised to use nasolacrimal occlusion or close the eyelids for 2 minutes after instillation. Excess solution should be wiped away to reduce the risk of darkening of eyelid skin. If more than one ophthalmic product is used, five minutes should separate their administration. Contact lenses should be removed before instillation. To prevent injury, avoid the container coming into contact with the eye and surrounding structures. If handled improperly, ocular solutions may become contaminated by common bacteria and cause serious damage to the eye.
Contraindications: Hypersensitivity to the active substances or to any of the excipients. Reactive airway disease including bronchial asthma, or a history of bronchial asthma, severe chronic obstructive pulmonary disease. Sinus bradycardia, sick sinus syndrome, including sino-atrial block and second or third degree atrioventricular block not controlled with pace-maker. Overt cardiac failure and cardiogenic shock.
Warnings and Precautions: The incidence of systemic adverse reactions to beta-adrenergic blocking agents after topical ophthalmic administration, is lower than following systemic administration. In patients with cardiovascular disease and hypotension, treatment with beta-blockers should be critically assessed and treatment with other substances considered. In patients with cardiovascular disease, signs of deterioration in their disease and adverse events should be checked. Only to be given with caution to patients with first degree heart block and severe peripheral circulatory disturbances / disorders such as Raynaud's disease / syndrome, and those with spontaneous hypoglycaemia / labile diabetes. Beta-blockers may mask the signs / symptoms of acute hypoglycaemia and hyperthyroidism. Administer with caution to patients with mild / moderate chronic obstructive pulmonary disease (COPD) and only if the potential benefit outweighs the potential risk. TAPTIQOM® may induce dry eyes. Treat with caution in patients with corneal disease. Patients receiving a systemic beta blocker should be closely observed for the effects of timolol on intra-ocular pressure or potentiation of the compound's systemic effect. Use of two topical beta adrenergic blocking agents is not recommended. Patients with a history of atopy or severe anaphylactic reaction may be more reactive to allergens and less responsive to the usual doses of adrenaline used to treat anaphylactic reactions. Anaesthetists should be informed when a patient is receiving timolol. When timolol is used to reduce elevated intraocular pressure in angleclosure glaucoma, always use a miotic. Before initiating treatment, patients should be informed of the possibility of eyelash growth, darkening of the eyelid skin and increased iris pigmentation related to tafluprost. These changes may be permanent, and lead to differences in appearance between the eyes if only one eye is treated. Hair growth may occur in areas where tafluprost comes into repeated contact with the skin surface. Caution is recommended when using tafluprost in aphakic patients, pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, and in patients with known risk factors for cystoid macular oedema or iritis/uveitis. There is no experience with tafluprost in neovascular, angle closure, narrow-angle or congenital glaucoma. Please see the SmPC for further information.
Interactions with other medicinal products: Potential for hypotension / marked bradycardia when administered with oral calcium channel blockers, beta-adrenergic blockers, anti-arrhythmics, digitalis glycosides, parasympathomimetics and guanethedine. A potentiation of the effects of systemic beta-blockers has been reported when combined with treatment with CYP2D6 inhibitors eg quinidine, fluoxetine, paroxetine and timolol. Mydriasis has been reported with the concomitant use of ophthalmic beta-blockers and adrenaline.
Pregnancy: Do not use in women of childbearing age/potential unless adequate contraceptive measures are in place. Breast-feeding: It is not recommended to breast-feed if treatment with TAPTIQOM® is required.
Driving and using machines: If transient blurred vision occurs on instillation, the patient should not drive or use machines until clear vision returns.
Undesirable Effects: Conjunctival/ ocular hyperaemia occurred in approximately 7% of patients participating in clinical studies with TAPTIQOM®. Other common side effects include: Eye pruritus, eye pain, change of eyelashes (increased length, thickness and number of lashes), eyelash discolouration, eye irritation, foreign body sensation, blurred vision, photophobia. Adverse reactions that have been seen with either of the active substances (tafluprost or timolol) and may potentially occur also with TAPTIQOM® include: *Ocular:* Reduced visual acuity, increased iris pigmentation, blepharal pigmentation, conjunctival oedema, eye discharge, anterior chamber cells/flare, allergic conjunctivitis, conjunctival pigmentation, conjunctival follicles deepening of eyelid sulcus, iritis/ uveitis, macular oedema/ cystoid macular oedema, hypertrichosis of eyelid, keratitis, decreased corneal sensitivity, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases), ptosis, diplopia, choroidal detachment following filtration surgery, *Non ocular:* exacerbation of asthma, dyspnoea, bronchospasm, respiratory failure, cough, allergy, angioedema, urticaria, anaphylaxis, localised/generalised rash, pruritus, hypoglycaemia, depression, insomnia, nightmares, memory loss, nervousness, hallucination, dizziness, syncope, paraesthesia, increase in signs and symptoms of myasthenia gravis, cerebrovascular accident, cerebral ischaemia, tinnitus, bradycardia, chest pain, palpitations, oedema, arrhythmia, congestive heart failure, cardiac arrest, heart block, atrioventricular block, cardiac failure, hypotension, claudication, Raynaud's phenomenon, cold hands and feet, nausea, dyspepsia, diarrhoea, dry mouth, dysgeusia, abdominal pain, vomiting, alopecia, psoriasiform rash or exacerbation of psoriasis, skin rash, SLE, myalgia, arthropathy, Peyronie's disease, decreased libido, sexual dysfunction, asthenia/fatigue, thirst. Please also see the SmPC.
Overdose: Treatment should be symptomatic and supportive.
Special Precautions for Storage: Store in a refrigerator (2°- 8°C). After opening the foil pouch keep the single-dose containers in the original pouch and do not store above 25°C. Discard open singledose containers with any remaining solution immediately after use.
MA Holder: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland
Package quantities and basic NHS cost: 30 x 0.3ml single-dose containers £14.50.
MA number: PL 16058/0012 **Date of Authorisation:** 11/09/2019
Legal Category: POM
Date of Prescribing Information: December 2021
Prescribing Information No: NP-TAPTIQ-UK-0017

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).

Santen

TAPTIQOM®
(15µg/ml tafluprost + 5mg/ml timolol maleate eye drops)

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

PRODUCT INFORMATION LEAFLET

Cationorm®

Eye drops, emulsion

Read all of this leaflet carefully before you start using this product.
Keep this leaflet; you may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
If symptoms persist, consult your doctor.

1. What Cationorm® is and what it is used for

Cationorm® is an ophthalmic sterile hypotonic preservative free eye drops emulsion in the form of a milky liquid.
Cationorm® contains: mineral oils, glycerol, tyloxapol, poloxamer 188, tris-hydrochloride, tromethamine, cetalkonium chloride (as cationic agent)] and purified water.
The bottle of Cationorm® contains 10 ml of sterile emulsion.
Cationorm® is intended for the treatment of dry eye symptoms such as stinging, itching or burning eyes or foreign body sensation (a feeling of sand or dust) in the eyes.
These symptoms may be caused by external factors, such as air conditioning, pollution, travel by plane, working on a screen, refractive surgery, contact lenses wear, etc., or by pathologies, such as meibomian gland dysfunction. Cationorm® hydrates, lubricates and protects the surface of the eye.

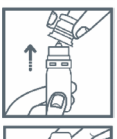
2. Before using Cationorm®

Do not use Cationorm® if you are allergic to any of the components of the product.
This product is not intended for treating other eye conditions. Please consult your doctor or pharmacist if you have any questions.
If you currently use other eye drops, you should wait at least 5 minutes between the administrations of each successive eye drop. It is recommended to use Cationorm® last.
Cationorm® is compatible with all kind of contact lenses.

3. How to use Cationorm®

OCULAR USE.
The recommended dose regimen is 1 drop in each eye, 1 to 4 times daily.
Instructions for use:

- Wash your hands.
- When you are using the eye drops bottle for the first time, remove the tamper-evident ring of the cap by pulling off the prominent strap.



- Open the bottle by gently pulling the cap.
- Grasp the body of the bottle between your thumb and forefinger.
- Avoid any contact of the tip of the bottle with your fingers.
- Tilt your head back.

- Gently pull down your lower eyelid and look up.
- Hold the bottle above the eye and place the back of your hand on your forehead.
- Gently squeeze 1 drop in the eye and blink several times.
- Do not touch the eye or eyelashes with the tip of the bottle.

- Put the cap back on the bottle after each use.
- Store the bottle in the box when you are not using it.

Do not use Cationorm® more than 3 months after the first opening.
The use of the bottle more than 3 months after the first opening exposes to a risk of infection.

4. What are the possible side effects

In very rare cases, a transient discomfort such as: eye irritation, eye pain, foreign body sensation in the eye, eye redness, eye itching, watery eyes, burning sensation in the eye, temporarily blurred vision, eyelids inflammation or eyelids edema can appear. These symptoms are also part of typical symptoms of dry eye disease linked to the underlying existing medical conditions in the patient's eyes suffering from dry eye. IF YOU NOTICE ANY SIDE EFFECTS THAT ARE NOT LISTED IN THIS LEAFLET, PLEASE INFORM YOUR DOCTOR OR PHARMACIST.

5. How to store Cationorm®

Store the bottle in its outer box at room temperature.
Keep out of the reach and sight of children.
Do not use if the bottle is damaged.
Do not use after the expiry date printed on the box. Use within 3 months after the first opening.
Write down the date of first opening of the bottle below:

This leaflet was last revised in March 2019.

Importer / Distributor:
SANTEN UK Limited
Salisbury Hall
St Albans AL2 1BU
United Kingdom

Manufacturer:
Santen
1, rue Pierre Fontaine
Bâtiment Genavenir IV
91000 Evry
France

CE 0459   STERILE A

Key:

Symbol				STERILE A	LOT			
Meaning	Manufacturer	Store below 30 °C	To be used within 3 months after 1st opening	Sterile via aseptic methods	Batch Number	Expiry Date	Read the Instructions for use	Do not use if the product sterile barrier system or its packaging is compromised

▼ 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

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).

Santen