

Latanoprost-netarsudil for previously treated primary open-angle glaucoma or ocular hypertension (NICE TA1009)

AMBER RECOMMENDED - specialist assessment and recommendation for non-specialist prescribing

Recommendations

The Cheshire and Merseyside Area Prescribing Group recommend the prescribing of latanoprost-netarsudil in accordance with NICE TA1009. NICE TA 1009 recommends latanoprost-netarsudil, within its marketing authorisation, as an option for reducing intraocular pressure (IOP) in adults with primary open-angle glaucoma or ocular hypertension when a prostaglandin analogue alone has not reduced IOP enough only if:

- they have then tried a fixed-dose combination treatment and it has not reduced IOP enough, or
- a fixed-dose combination treatment containing beta-blockers is unsuitable [1].

Prescribing information [2]

The recommended dose for latanoprost-netarsudil is 1 drop in to the affected eye(s) once daily in the evening.

Contact lenses should be removed prior to instillation of the eye drop and may be reinserted 15 minutes following administration.

The tip of the dispensing container should avoid contacting the eye, surrounding structures, fingers or any other surface in order to avoid contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

If latanoprost-netarsudil is to be used with other topical ophthalmic medicinal products, each medicinal product should be administered at least 5 minutes apart. Other eye drops should be administered before latanoprost-netarsudil and eye ointments should be administered after.

Implementation notes

Treatment with latanoprost-netarsudil should be initiated on the recommendation of a specialist in either primary or secondary care.

Patient factors [2]

The safety and efficacy of latanoprost-netarsudil has not been established in children below the age of 18 years old.

No dose adjustment is required in either hepatic impairment or renal impairment.

Safety [2]

Contraindications:

Hypersensitivity to the active substance(s) or to any of the excipients.

ICB approval date: 21 Nov 2024 Version 1.0 Review Nov 2026 or earlier if there is significant new evidence relating to this recommendation

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Cautions:

Iris pigmentation - latanoprost may gradually change eye colour by increasing the amount of brown pigment in the iris. Patients should be informed of this before initiating treatment.

Herpetic keratitis - medicinal products containing latanoprost should be used in caution 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 - reports of macular oedema with medicinal products containing latanoprost have occurred mainly in aphakic patients, in pseudophakic patients with torn posterior lens capsules or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema (such as diabetic retinopathy and retinal vein occlusion).

Asthma exacerbation - there is limited experience of latanoprost use in patients with asthma, but some cases of exacerbation of asthma and/or dyspnoea were reported in post marketing experience. Asthmatic patients should therefore be treated with caution until there is sufficient experience with the combination.

Iritis/uveitis risk - in patients with known predisposing risk factors for iritis/uveitis, medicinal products containing latanoprost can be used with caution.

Periorbital skin discolouration - this has been observed on treatment with medicinal products containing latanoprost, most reports being in Japanese patients. Experience to date shows that periorbital skin discolouration is not permanent and, in some cases, has reversed while continuing treatment with latanoprost.

Eyelash changes - treatment with medicinal products containing latanoprost may gradually change eyelashes and vellus hair in the treated eye and surrounding areas; these changes include increased length, thickness, pigmentation, number of lashes or hairs and misdirected growth of eyelashes. Eyelash changes are reversible upon discontinuation or treatment.

Benzalkonium chloride content - benzalkonium chloride has been reported to 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 patients with dry eye and in patients where the cornea may be compromised.

Side effects:

The common adverse effects when using latanoprost-netarsudil include dry eye, eye discomfort, eye disorders, eye inflammation, haemorrhage, skin reactions and vision disorders. Refer to the <u>SPC</u> for a full list

Pregnancy - there are no or limited amount of data from the use of latanoprost-netarsudil in pregnant women, therefore latanoprost-netarsudil is not recommended for use during pregnancy.

Breastfeeding - it is unknown whether netarsudil or itsmetabolites are excreted in human milk. However, while no effects on the breastfed newborn/infant are anticipated since the systemic exposure of breastfeeding individuals to netarsudil is expected to be negligible, no relevant clinical data are available. Latanoprost or itsmetabolites may pass into human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from taking this treatment taking into account the benefit of breastfeeding for the child and the benefit of therapy for the individual.

Fertility - there are no data on the effects of netarsudil on male or female fertility. However, no effects are anticipated since systemic exposure to netarsudil is negligible. Latanoprost has not been found to have any effect on male or female fertility in animal studies.

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Interactions - administer other eye drops at least 5 minutes apart. There have also been reports of paradoxical elevations in IOP following the concomitant ophthalmic administration of two prostaglandin analogues. Therefore, the use of two or more prostaglandins, prostaglandin analogues or prostaglandin derivatives is not recommended.

The efficacy of latanoprost-netarsudil has not been studied beyond 12 months.

Cost

The NHS list price is £14.00 per 2.5mL bottle (excluding VAT) [3]. The annual treatment cost per patient is £168.

As this is a step-up treatment, cost comparison to other treatments is not indicated.

Based on assumptions within the NICE resource impact template for TA1009, the estimated cost of implementing this guidance in Cheshire and Merseyside is £10,000 in 2025-26, £19,000 in 2026-27, £30,000 in 2027-28, £39,000 in 2028-29 and £51,000 in 2029-30 when it is assumed that steady state is reached. This is based on drug cost alone [1].

Effectiveness

Latanoprost-netarsudil contains two active substances, latanoprost and netarsudil. Latanoprost is a prostaglandin $F2\alpha$ analogue which reduces the intraocular pressure by increasing the outflow of the aqueous humour. Netarsudil is a Rho kinase inhibitor which reduces the intraocular pressure by increasing trabecular outflow and reducing episcleral venous pressure [2].

The clinical data for latanoprost-netarsudil came from MERCURY 3, a phase 3, double-blind, randomised controlled trial comparing latanoprost-netarsudil with bimatoprost-timolol. It included adults with primary open angle glaucoma or ocular hypertension in both eyes who had previous monotherapy and were considered by the investigators to need combination treatment. Their medicated IOP was 17mmHg or more in at least 1 eye and below 28mmHg in both eyes at the initial screening. The primary endpoint in MERCURY 3 was mean IOP within each treatment group at the following time points: 8am, 10am and 4pm at the week 2, week 6 and month 3 study visits. Clinical non-inferiority of latanoprost-netarsudil relative to bimatoprost-timolol was shown with the upper limit of the 95% confidence intervals being: 1.5mmHg or lower at all time points and 1.0mmHg or lower at 6 out of 9 time points from week 2 through to month 3 [1].

References

- National Institute of Health and Care Excellence. Technology Appraisal 1009. <u>Latanoprost-netarsudil for previously treated primary open-angle glaucoma or ocular hypertension</u>. Published 2 October 2024. Accessed 03/10/2024.
- 2. Santen UK Limited. Summary of Product Characteristics; Roclanda 50 micrograms/ml + 200 micrograms/ml eye drops, (solution) 25 May 2023. Accessed 03/10/2024
- 3. NHS Business Services Authority. <u>Roclanda 50micrograms/ml + 200micrograms/ml eye drops dm+d browser (nhsbsa.nhs.uk)</u>. Accessed 03/10/2024.

Patients who are not eligible for treatment under this policy may still be considered for treatment on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Follow the locally defined process.