

Rocklatan[™] (netarsudil and latanoprost) – New drug approval

- On March 12, 2019, <u>Aerie Pharmaceuticals announced</u> the FDA approval of <u>Rocklatan (netarsudil and latanoprost)</u> 0.02%/0.005% ophthalmic solution, for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension.
- Glaucoma is a disease that causes damage to the optic nerve. It is characterized by progressive degeneration of retinal cells, resulting in irreversible vision loss and, potentially, blindness. The National Eye Institute estimates that more than 2.7 million people in the U.S. suffer from glaucoma, a number expected to reach 4.3 million by 2030.
- Rocklatan is a fixed-dose combination of <u>latanoprost</u>, a prostaglandin analog, and netarsudil, the
 active ingredient in <u>Rhopressa</u>[®], a first-in-class Rho kinase inhibitor specifically designed to target the
 trabecular meshwork (the eye's principal drainage pathway).
- The efficacy of Rocklatan was established in two clinical studies (study 301 and 302) in patients with OAG and ocular hypertension. Patients were randomized to Rocklatan, netarsudil 0.02%, or latanoprost 0.005% once daily. The primary endpoint was IOP lowering effect.
 - The average IOP lowering effect of Rocklatan was 1 to 3 mmHg greater than monotherapy with either netarsudil or latanoprost throughout 3 months.
 - In study 301, IOP reductions were maintained throughout 12 months.
- Warnings and precautions of Rocklatan include pigmentation, eyelash changes, intraocular inflammation, macular edema, herpetic keratitis, bacterial keratitis, and use with contact lenses.
- The most common adverse reaction with Rocklatan use was conjunctival hyperemia (59%). Other common adverse reactions were: instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%).
- The recommended dosage of Rocklatan is one drop in the affected eye(s) once daily in the evening.
 - If one dose is missed, treatment should continue with the next dose in the evening. The dosage of Rocklatan should not exceed once daily.
- Aerie Pharmaceuticals plans to launch Rocklatan in the second quarter of 2019. Rocklatan will be available as a netarsudil 0.02%/latanoprost 0.005% ophthalmic solution.



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