



PDL NEW DRUG REVIEW

Proprietary Name: Rescula®

Common Name: unoprostone isopropyl

PDL Category: Ophthalmic-Glaucoma Agents

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Alphagan P	Preferred
Latanoprost	Preferred
Timolol maleate	Preferred
Travatan Z	Preferred

Summary

Indications and Usage: For the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. This is a pregnancy category C medication. The safety and efficacy of use in children under 18 years of age has not been established.

Drug Interactions: There are no documented drug interactions.

Dosage Forms: Ophthalmic solution: 1.5mg/ml

Recommended Dosage: Recommended to instill one drop into the affected eye(s) twice daily. The dropper tip should not touch the eyelids or surrounding areas to help minimize contaminating the dropper tip and solution. As this solution contains benzalkonium chloride, contact lens should be removed prior to instillation of drops but may be reinserted 15 minutes following its administration.

Common Adverse Drug Reactions: *There was no placebo data available.* The most common adverse events reported in approximately 10-25% included burning/stinging, burning/stinging upon instillation, dry eyes, itching, increased length of eyelashes, and injection. Approximately 10-14% reported an increase in the length of eyelashes $\geq 1\text{mm}$ at 12 months and 7% reported a decrease in the length of eyelashes. Approximately 5-10% reported abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder. Approximately 1-5% reported blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.

Non-ocular adverse events reported by 1-5% included accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis. Flu-like syndrome was reported by 6%.

Iris and lid pigmentation may occur with unoprostone isopropyl. Lid pigmentation has been reported to be reversible upon discontinuation of treatment in most patients.

Macular edema, including cystoid macular edema, has been reported with use. Rescula® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in those with known risk factors for macular edema.

Contraindications: In those with hypersensitivity to the active ingredient or any component of the product

Manufacturer: Sucampo Pharma Americas, LLC

Analysis: Unoprostone isopropyl, the active ingredient of Rescula®, is a synthetic docosanoid. Its exact mechanism of action is not known; however, it is thought to reduce intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork. Six month randomized controlled studies were performed to assess efficacy in patients with a mean baseline IOP of 23mmHg. Treatment results suggested a 3-4mmHg reduction in IOP throughout the day. Results also suggested no effect on cardiovascular or pulmonary function.

A 2005 study by Leelachaikul et al² included 22 patients (44 eyes) with uncontrolled IOP (≥ 22 mmHg) while on topical beta-blocker monotherapy or IOP levels ≥ 18 mmHg while on dual therapy (topical beta-blocker and a second topical which was to be discontinued prior to the study, allowing for wash-out effects). When unoprostone was added to beta-blocker therapy, there was a statistically significant reduction in IOP of 24.6% ($p < 0.01$).

There is no evidence at this time to support that Rescula® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Rescula® remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

PDL Placement:

- Preferred
- Non-Preferred
- Preferred with Conditions

References

¹ Rescula [package insert]. Bethesda, MD: Sucampo Pharma Americas, LLC; 2013.

² Leelachaikul Y, Euswas A. The efficacy of unoprostone isopropyl as an adjunct to topical beta-blocker in patients with open angle glaucoma: a 6-month study. *J Med Assoc Thai*. 2005; 88 Suppl 9: S100-4.