

Supplemental Approvals

Generic Name (Trade Name—Company)

September 26, 2018

Latanoprost ophthalmic emulsion 0.005%

(Xelpros—Sun Pharma)

Topical formulation reduces IOP in open-angle glaucoma or ocular hypertension

Uses/Notes

Sun Pharma [announced](#) FDA approval of latanoprost ophthalmic emulsion 0.005% for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

It is the first and only form of latanoprost that is not formulated with benzalkonium chloride, a preservative commonly used in topical ocular preparations.

Recommended dosage 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 as normal. Reduction of IOP starts approximately 3 to 4 hours after administration, and the maximum effect is reached after 8 to 12 hours.

In clinical trials, the most frequently reported adverse reactions were eye pain/stinging upon instillation and ocular hyperemia (redness).

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