



Photrexa[®] Viscous (riboflavin 5'-phosphate in 20% dextran) and Photrexa[®] (riboflavin 5'-phosphate) – New Orphan Drug Approvals

- On April 19, 2016, [Avedro announced the FDA approval of Photrexa Viscous \(riboflavin 5'-phosphate in 20% dextran\) and Photrexa \(riboflavin 5'-phosphate\)](#) indicated for topical ophthalmic use with the [KXL[™] System](#) in corneal collagen cross-linking for the treatment of progressive keratoconus.
- [Keratoconus](#) is a progressive thinning and distortion of the cornea. It produces blurred and distorted vision that is difficult to correct with eyeglasses. Corneal implants may be needed. Keratoconus is the most common corneal dystrophy in the U.S., affecting 1 of every 2,000 people.
- Corneal collagen crosslinking aims to halt the progress of keratoconus by strengthening chemical bonds in the cornea. Crosslinking may prevent the need for corneal implants.
- The efficacy and safety of Photrexa Viscous/Photrexa were demonstrated in 3 prospective, randomized, open-label, and sham-controlled trials. Study 1 enrolled 58 patients and study 2 enrolled 147 patients with progressive keratoconus. Maximum corneal curvature (Kmax) was assessed at baseline and at 12 months.
 - At 12 months, an average Kmax reduction of 1.4 diopter and 1.7 diopter was seen in Photrexa-treated eyes in study 1 and study 2, respectively.
 - In the sham-treated eyes, an average increase of 0.5 diopter and 0.6 diopter in study 1 and study 2, respectively, was seen at 12 months.
 - The difference between the Photrexa- and sham-treated groups was -1.9 diopters (95% CI: -3.4, -0.3) and -2.3 diopters (95% CI: -3.5, -1.0), in study 1 and study 2, respectively.
- Warnings and precautions of Photrexa Viscous and Photrexa include ulcerative keratitis.
- The most common adverse events with Photrexa Viscous and Photrexa use were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.
- Photrexa Viscous and Photrexa are for use with the KXL System only. Photrexa and Photrexa Viscous are administered during the corneal cross-linking procedure. Refer to the prescribing information for specific dosage and administration instructions.
- Avedro plans to launch Photrexa Viscous and Photrexa by the end of the year. Photrexa Viscous will be available as a 3 mL glass syringe containing 1.46 mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution. Photrexa will be available as a 3 mL glass syringe containing 1.46 mg/mL riboflavin 5'-phosphate ophthalmic solution.



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