



## Photrexa<sup>®</sup> Viscous (riboflavin 5'-phosphate in 20% dextran) and Photrexa<sup>®</sup> (riboflavin 5'-phosphate) – New Indication

- On July 19, 2016, [Avedro announced](#) the FDA approval of [Photrexa Viscous \(riboflavin 5'-phosphate in 20% dextran\)](#) and [Photrexa \(riboflavin 5'-phosphate\)](#) for ophthalmic use with the KXL<sup>®</sup> System in corneal collagen cross-linking (CXL) for the treatment of corneal ectasia following refractive surgery.
  - Photrexa Viscous and Photrexa with the KXL System in CXL are also indicated for the treatment of progressive keratoconus.
- Corneal ectasia is a rare but serious complication of vision correction procedures. The weakened cornea loses its shape and bulges forward, resulting in distorted vision that cannot be corrected with eyeglasses. Cornea ectasia is estimated to affect about 160,000 people in the U.S.
- The efficacy and safety of Photrexa Viscous/Photrexa were demonstrated in 3 prospective, randomized, open-label, and sham-controlled trials. Study 1 enrolled 49 patients and study 3 enrolled 130 patients with corneal ectasia. Maximum corneal curvature (Kmax) was assessed at baseline and at 12 months.
  - At 12 months, an average Kmax reduction of 1.0 diopter and 0.5 diopter was seen in Photrexa-treated eyes in study 1 and study 3, respectively.
  - In the sham-treated eyes, an average increase of 1.0 diopter and 0.5 diopter in study 1 and study 3, respectively, was seen at 12 months.
  - The difference between the Photrexa- and sham-treated groups was -2.0 diopters (95% CI: -3.0, -1.1) and -1.1 diopters (95% CI: -1.9, -0.3), in study 1 and study 3, respectively.
- Photrexa Viscous and Photrexa are for use with the KXL System only. Photrexa and Photrexa Viscous are administered during the CXL procedure. Refer to the prescribing information for specific dosage and administration instructions.
- Avedro plans to launch Photrexa Viscous and Photrexa in early fall of 2016.



OptumRx<sup>®</sup> specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum<sup>®</sup> company — a leading provider of integrated health services. Learn more at [optum.com](http://optum.com).

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

Rx News<sup>®</sup> is published by the OptumRx Clinical Services Department.

©2016 Optum, Inc. All rights reserved.