

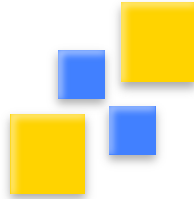
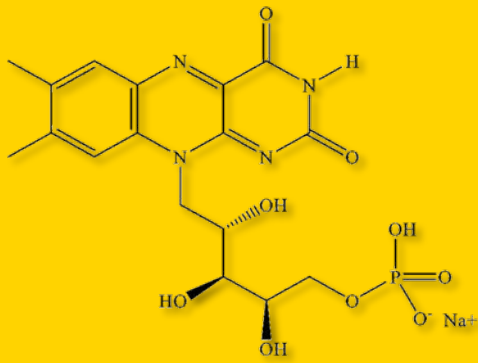
# RIBOLEX™



## ULTRA PURE CXL RIBOFLAVIN SOLUTIONS

RIBOLEX™ is simply the purest most refined composition which has been used by thousands of ophthalmologists world-wide for well over 10 years, assuring controllable, efficient and safe corneal cross linking (CXL) procedures.

Manufactured under the most stringent of GMP practices in Australia, Ribolex remains the highest grade compound of choice for the most discerning physicians, available in 5 formulations and compatible for use with all types corneal cross linking Devices.



## unsurpassed quality, tailor-made solutions...

GD Pharma is a specialty pharmaceutical company dedicated to improve the lives of patients by providing new, high quality, innovative pharmaceutical products and tailored pharmaceutical and vitamin compounding solutions.

The company addresses critical unmet medical needs for niche markets focusing on rapid and highly customized development, manufacture and marketing conventional and novel drug formulations and drug delivery systems.

GD Pharma works collaboratively with its clients and global partners to tailor-make solutions for their needs, and prides itself on consistently achieving and maintaining the highest quality standards.

Fully compliant and registered with the Good Manufacturing Practice (GMP) regulations, and Therapeutic Goods Administration (TGA), the facility allows us to rapidly fill a range of products for clients including sterile and non-sterile liquid pharmaceuticals, in large to small batch volumes not viable for most Pharma manufacturers.

Riboflavin (Vitamin B2) solution ensures a fundamental role in cross-linking procedure acting as a photosensitizer, where once activated by the UV-A irradiation, it produces free radicals which lead to the formation of molecular bridges (cross-links) between and within collagen fibrils, significantly enhancing the corneal biomechanical stability.

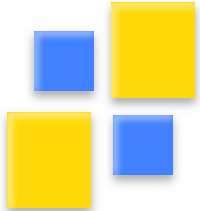
The second role of Riboflavin is the UV-A shielding, as it absorbs the ultraviolet light generated by the cross linking device, hence reducing the risk of UV-A related damage to corneal endothelium, lens and retina.

RIBOLEX™ solution is consistently used by thousands of physicians all over the globe and it has been continually regarded as the most refined composition assuring optimum corneal cross-linking procedure outcomes.

The same compound continues and has been offered for well over 10 years as an OEM solution for many other renowned brands in the cross linking market, now available under the Proprietary brand assuring outstanding value with unsurpassed quality.



**RIBOLEX™**  
**RIBOFLEX™**



### ISOTONIC

**APPLICATION:** CXL treatment of Normal Corneas with thickness of 400µm and above.

- Epi-off treatment, Recommended application time: 20 – 25 minutes.
- (Recommended instilment: 1 drop every 2 to 3 minutes)

**COMPOSITION:** (0.1%) Riboflavin (Vitamin B2) with 20% Dextran T500

**PRESENTATION:** In 3ml sterile glass syringe applicator / individually sealed in sterile pouch.

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### HYPOTONIC

**APPLICATION:** CXL treatment of Corneas with thickness below 400µm by osmotic swelling effect.

- Epi-off Treatment; Recommended application time: 1 drop every 5 seconds until corneal thickness has reached recommended safe thickness of 400µm.
- During Cross-linking procedure follow with Hypotonic drop every 2 minutes or in combination with Isotonic compound to maintain thickness at 400µm.

**COMPOSITION:** (0.1%) Riboflavin (Vitamin B2)

**PRESENTATION:** In 1.5ml sterile glass syringe applicator / individually sealed in sterile pouch.

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### TRANS EPITHELIAL (TE)

**APPLICATION:** Trans-Epithelial CXL procedure without removal (scrape) of the corneal epithelium.

- Transepithelial ‘Epi-On’ treatment; Recommended application time: 7 -15 minutes
- (1 drop every 90 seconds)

**COMPOSITION:** 0.25 % Riboflavin, 1.1 % HPMC 0.01 % Benzalkoniumchloride (BAC)

**PRESENTATION:** In 2ml sterile glass syringe applicator / individually sealed in sterile pouch.

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### RAPID

**APPLICATION:** Faster Diffusion (soaking) and for Accelerated (higher irradiation) Cross Linking procedure.

- Epi-off treatment; Recommended application time: 7 -15 minutes (1 drop every 90 seconds)

**COMPOSITION:** (0.1%) Riboflavin (Vitamin B2), HPMC, NaCl, Na2HPO4

**PRESENTATION:** In 2ml sterile glass syringe applicator / individually sealed in sterile pouch.

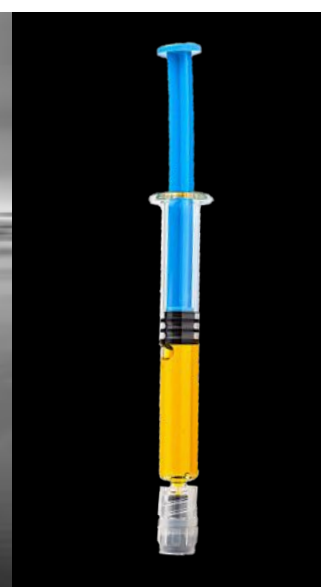
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### PLUS

**APPLICATION:** LASIK-extension procedure for prevention of post-LASIK ectasia and enhanced biomechanical stability.

- Application on Stromal bed.
- Recommended usage: After flap preparations & excimer treatment , apply 3 to 5 drops Riboflavin on the stroma. Reapply the flap back on, wait 4 minutes, then reopen flap and rinse off Riboflavin.
- Close the flap back and radiate with ½ (half) of the recommended treatment irradiation energy.

- **COMPOSITION:** 0.25 % Riboflavin (Vitamin B2)
- **PRESENTATION:** In 2ml sterile glass syringe applicator / individually sealed in sterile pouch.



## INDICATIONS:

Ribolex solutions are considered as topical use, non-pharmaceutical Vitamin B2 agents indicated for topical use in treatment of progressive keratoconus and cornea ectasia as extension of refractive surgery. Suitable for use in conjunction with all commercially available corneal collagen cross-linking devices.

## WARNING AND PRECAUTIONS

There have not been any side effects related specifically to Ribolex compound. However in corneal cross-linking procedure as whole adverse reactions are rare although may result in corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, some reduced visual acuity. For more information, the physician must refer to Prescribing Information and specific corresponding Corneal Cross-Link device operator's manual.

## DISCLAIMER:

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- RIBOLEX™ is a registered trademark of Ribolex Pty. Ltd.
- Compounded and distributed as non-pharmaceutical, under GD Pharma Therapeutic Goods Administration (TGA) Australia GMP license MI-2012-LI-00154-3 and a license 2013-80648 to manufacture controlled substance medicines.
- Not available for commercial sale in USA, non-FDA approved.

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# RIBOLEX™



MADE IN AUSTRALIA