

Instructions For Use

VibeX Rapid

Riboflavin Solution for Accelerated Corneal Cross-Linking
For epithelium-off procedure

Contents:

VibeX Rapid syringe (1) with ophthalmic cannula (1) – Syringe filled with 1.5ml VibeX Rapid solution

FOR SINGLE USE ONLY

Composition (per 100 ml):

- 0.1% Riboflavin
- Hydroxypropyl Methylcellulose (HPMC)
- Sodium Chloride
- Disodium hydrogenphosphate x 12 H₂O
- Sodium dihydrogenphosphate x 2 H₂O
- Water for injection

Usage:

1. With the patient supine, remove corneal epithelium over the desired area.
2. Apply sufficient VibeX Rapid to completely wet and cover the exposed stroma. Repeat VibeX Rapid application at least once every 2 minutes for a total of up to 10 minutes depending on the desired depth of crosslinking.
3. Measure corneal thickness to ensure that it is greater than 325 µm. If corneal thickness is less than 325 µm, use standard clinical techniques
4. to increase the corneal thickness.
5. Once the correct corneal thickness has been verified, apply VibeX Rapid and then initiate UV treatment
6. Initiate UV treatment.
7. Complete the procedure using standard clinical techniques.

Indications:

- Corneal strengthening
- Progressive keratoconus
- Iatrogenic ectasia
- Pellucid marginal degeneration

Contraindications:

- Corneal thickness, with epithelium, less than 375 µm
- Pregnancy
- Epithelial healing problems
- Refractive keratotomy
- Herpetic keratitis (UV can activate herpes)
- Rheumatic disorders
- Known sensitivity to any of the ingredients
- Corneal melting

Characteristics:

- Riboflavin (vitamin B2) is a water-soluble yellow substance.
- HPMC is a polymer that can be used for adjusting viscosity of the solution.

Storage:

- Store in dark place
- Storage temperature ≤ 28° C
- Discard solution 12 hours after opening outer package
- See expiry date
- Sterile if package is not broken, do not use if package is damaged
- Do not remove from dark bag prior to use.

Side effects: (adverse effects without specifying the frequency)

- Hypersensitivity reactions (burning) may occur **temporarily**. These usually resolve after discontinuation.


Possible risks: (without specifying the frequency)

- Corneal oedema
- Stromal scarring
- Inclusions
- Corneal Haze
- Keratitis by bacteria
- Sterile infiltrates
- Corneal Calcification

Other information:

- VibeX Rapid is a sterile medical device (CE 0482).
- 1 syringe for use for one eye only.
- Any remaining solution should be discarded.
- Use as directed. Medio-Haus Medizinprodukte GmbH cannot guarantee the warranted characteristics such as function, material properties or sterility if product is used in a manner that is not consistent with Usage described above, or if the product is reused.

Manufacturer:  0482

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LOT

Manufacturing LOT



Best before



See directions for use



Single use only



Steam-sterilized



Storage not over 28°C



End packed product sterilized with Ethylene Oxide



Store in the dark

LBL-00132 Rev J