

Instructions For Use

MedioCROSS® M

Riboflavin Solution for Corneal Cross-Linking

For epithelium-off procedure

Contents:

- MedioCROSS M syringe (1) with dropping adapter (1) – Syringe filled with 3.0ml (~60 drops) MedioCROSS M

Note to the Doctor:

- FOR SINGLE USE ONLY
- FOR TOPICAL OPHTHALMIC USE ONLY
- NO SIMULTANEOUS APPLICATION OF ANOTHER THERAPEUTIC OPHTHALMIC MEDICATION

Composition (per 100 ml):

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

Usage:

1. After removal of the corneal epithelium, apply sufficient MedioCROSS M to completely wet and cover the exposed stroma at two-minute intervals for a total of up to 10 minutes.
2. Check corneal thickness by means of ultrasound pachymetry. If corneal thickness is less than 325 µm corneal thickness must be increased by means of MedioCROSS H (hypotonic riboflavin solution) to ensure endothelial safety.
3. After reaching a corneal thickness of at least 325 µm radiation, start UV treatment.
4. When radiation stops, clean eye with (chilled) saline solution.
5. Insert bandage contact lens.
6. **Apply antibiotic ointment.**

Indications:

- Progressive keratoconus
- Iatrogenic ectasia
- Pellucid marginal degeneration

Contraindications:

- Epithelial healing problems
- Corneal melting
- Pregnancy
- Herpetic keratitis (UV can activate herpes)
- Rheumatic disorders
- Known sensitivity against one of the ingredients

Note to the Patient:

- AFTER APPLICATION THE VISUAL ACUITY IS TEMPORARILY REDUCED.
- DO NOT DRIVE, DO NOT USE ANY MACHINERY, AND WAIT UNTIL THE NORMAL VISUAL ACUITY HAS BEEN RESTORED.

Characteristics:

- Riboflavin (vitamin B2) is a water-soluble yellow substance
- Hydroxypropylmethylcellulose (HPMC) is a white powder

Storage:

- Store in dark place
- Storage temperature ≤ 25° 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 foil pouch 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 staining
- Keratitis by bacteria
- Sterile infiltrates
- Corneal opacity
- Corneal oedema
- Stromal scarring
- Inclusions

Other information:

- MedioCROSS M is a sterile medical device (CE 0482).
- **1 syringe of MedioCROSS M is 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

 Medio-Haus Medizinprodukte GmbH
Brunswiker Straße 50, 24105 Kiel, Germany

Distributed by:
Avedro, Inc.
201 Jones Road, 5th Floor West, Waltham, MA, 02451 USA

 LOT

Manufacturing LOT



Best before



See directions for use



Single use only



Steam-sterilized



Storage not over 25°C



Endpacked product sterilized with Ethylene Oxide



Store in the dark

LBL-00333 Rev C