

Instructions For Use

MedioCROSS® H

Riboflavin Solution for Corneal Cross-Linking

For epithelium-off or epithelium-on procedures

Contents:

- MedioCROSS H syringe (1) – Syringe filled with 1.5 ml (~100 drops) MedioCROSS H

Note to the Doctor:

- FOR SINGLE USE ONLY
- TO BE USED IN EPI-ON AND EPI-OFF PROCEDURES
- NO SIMULTANEOUS APPLICATION OF ANOTHER THERAPEUTIC OPHTHALMIC MEDICATION

Composition (per 100 ml):

- 0.1% Riboflavin
- Water for injection

Usage:

1. Check corneal thickness after instillation of MedioCROSS (D/M) by means of ultrasound pachymetry. If corneal thickness is less than 400 µm corneal thickness must be increased by means of MedioCROSS H (hypotonic riboflavin solution) to ensure endothelial safety.
2. Apply two drops MedioCROSS H every 5 to 10 seconds until the corneal thickness increases to at least 400 µm. This step may be faster if the eyelid speculum is removed from the patient's eye and the patient is allowed to close his/her eye in between drop applications.
3. After reaching a corneal thickness of at least 400 µm radiation treatment with a UV-radiation system can start.
4. Continue instilling 1 drop MedioCROSS (D/M) according to instructions.
5. When radiation stops clean eye with (chilled) saline solution. (UV time depends on UV system used & procedure detailed in system manual).
6. Insert bandage contact lens when using MedioCROSS D, MedioCROSS M.
7. 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
- Simultaneous application of other or additional eye medicine

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

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

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LOT

Manufacturing LOT



See directions for use

STERILE 

Steam-sterilized

STERILE 

Endpacked product
sterilized with Ethylene
Oxide



Best before



Single use only



Storage not over 25°C



Store in the dark

LBL-00334 Rev E