

## Instructions For Use

# MedioCROSS® TE

### Riboflavin Solution for Corneal Cross-Linking

For *trans-epithelium (epi-on) procedure*

#### Contents:

- MedioCROSS TE syringe (1) with dropping adapter (1) – Syringe filled with 2.0 ml (~40 drops) MedioCROSS TE

#### Note to the Doctor:

- **FOR SINGLE USE ONLY**
- **TO BE USED ONLY IN EYES WITH INTACT EPITHELIUM**
- **NO SIMULTANEOUS APPLICATION OF ANOTHER THERAPEUTIC OPHTHALMIC MEDICATION**

#### Composition (per 100 ml):

- 0.25% Riboflavin
- Hydroxypropylmethylcellulose (HPMC)
- Benzalkoniumchloride
- Sodium Chloride
- Disodium hydrogenphosphate x 12H<sub>2</sub>O
- Sodium dihydrogenphosphate x 2H<sub>2</sub>O
- Water for injection

#### Usage:

##### **For surface applications:**

1. **Do not remove corneal epithelium.**
2. Ensure that the patient is in a supine position on a patient table or chair.
3. Measure corneal thickness with ultrasound pachymeter. If corneal thickness is less than 400 µm increase corneal thickness by means of MedioCROSS H (hypotonic riboflavin solution) to ensure endothelial safety.
4. Apply sufficient MedioCROSS TE to completely cover the whole cornea and repeat this procedure every 2 minutes for at least 20 minutes. Instruct the patient to keep his eyes closed between applications.
5. Apply a topical anaesthetic to the cornea as needed.
6. Apply a lid speculum using standard clinical techniques.
7. Flush the cornea completely with BSS.
8. Initiate UV treatment (with e.g. CCL-Vario, CCL-365, XLink®, KERA-X, UV-X®).
9. Wet the cornea with BSS as needed.
10. Complete the procedure using standard clinical techniques.

#### Indications:

- Progressive keratoconus
- Iatrogenic ectasia
- Pellucid marginal degeneration

#### Contraindications:

- Corneal thickness, with epithelium, less than 400 µm
- Epithelial healing problems
- Refractive keratotomy (Intra PRK, LASIK Xtra)
- Corneal melting
- Pregnancy, nursing women, children
- Herpetic keratitis (UV can activate herpes)
- Rheumatic disorders
- Known sensitivity against one of the ingredients
- Simultaneous application of other or additional eye medicine

**Manufacturer:**  0482



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#### 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 calcification
- Corneal oedema
- Stromal scarring
- Inclusions

#### Other information:

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



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-00335 Rev D