

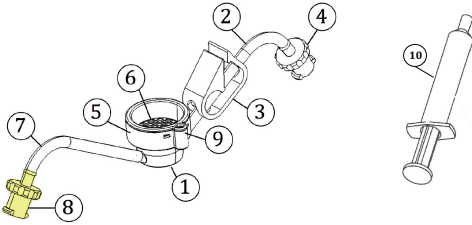
## CORNEAL IONTOPHORESIS APPLICATOR

Device specially designed for the transepithelial delivery of Riboflavin (0.1%) in the cornea for the treatment of infectious keratitis by mean of cross-linking in veterinary field. The corneal iontophoresis applicator is adapted for corneas with a diameter above 12,5 mm.

**Description**

The corneal iontophoresis applicator is an electrode that enables the rapid passage of Riboflavin through the epithelium into the corneal stroma by creation of an electric field of low intensity. The soaking of cornea with riboflavin, in association with ophthalmic UV-A radiations, is indicated for the treatment of infectious keratitis associated or not with corneal melting. The transepithelial penetration of Riboflavin, favoured by the electrical field of low intensity, improve the corneal cross-linking procedure by shortening the Riboflavin soaking time and by avoiding the need of de-epithelialization. This contributes to reduce the patient discomfort during postoperative healing.

The corneal iontophoresis applicator consists in:



- A vacuum ring (1) that enables the device to be fixed onto the eye during the procedure.
- A tube (2) for air suction, which can be clamped (3).
- A female Luer-lock connector (4) to plug the vacuum syringe (10) supplied with the applicator.
- A reservoir (5) that must be filled with RiboVet.
- A mesh electrode (6) on the top of the reservoir to deliver current to the RiboVet solution.
- Another tube (7) with a yellow female Luer-lock connector (8) to empty the reservoir (5) of RiboVet.
- An electrical connector (9) to connect with the I-ON CXL<sup>®</sup> current generator (refer to the required material for the procedure).
- A vacuum syringe (10) to perform the vacuum.

**Indications**

The corneal iontophoresis applicator is used for the administration of a riboflavin solution into the corneal stroma. The soaking of the cornea with riboflavin, in association with ophthalmic UV-A radiations, is indicated for the treatment of infectious keratitis and corneal melting.

In particular, the treatment is indicated in the following conditions:

- For infectious keratitis not responding to antimicrobial therapy.
- For severe infectious keratitis associated with corneal melting, to avoid emergency keratoplasty.

The treatment (UV-A + Riboflavin) is intended to cure infectious keratitis. The treatment can manage the infection and slow down the ulceration process before to perform keratoplasty. The treatment can stop the melting process. The treatment dose not exclude the possible need of keratoplasty in the future.

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18. Rinse the patient eye with a saline solution.

19. Proceed immediately with the irradiation using the UV-A emitter (refer to the instructions for use of the device).

20. Discard the corneal applicator, hypodermic needle and vacuum syringe according to standard operating procedures.

*Note: If the iontophoresis treatment should be stopped during procedure for any reason, put the generator in PAUSE mode according to the generator instructions before removing the corneal applicator from the eye.*

**Contraindications**

The corneal iontophoresis applicator is contraindicated for use on patients with:

- With ocular dimensions not fitting with the size of the corneal applicator.

*It is recommended not to treat patients with the following pathologies:*

- Severe lesions of the eyelid that may hamper the proper positioning of the corneal applicator.
- Corneal perforation.

**Risks associated with the procedure**

Ocular burns, skin irritation or burns.

**Predictable adverse secondary effects**

Slight epithelial lesions. Fibrosis tissue at the initial location of the lesion.

**Caution**

- This device is intended to be used by veterinarian only.
- Do not use on corneas which diameter is less than 12,5 mm.
- Respect Instructions for Use.
- Do not use fluorescein before treatment.
- If a topical antimicrobial treatment is ongoing, verify that there is no interaction with riboflavin absorption spectrum.
- If any doubt, stop topical antimicrobials administration 24 hours before treatment.
- Do not reuse: this could cause cross infections.
- Use only with the RiboVet solution supplied.
- Do not resterilize.
- Do not use on another body part.
- Do not use the corneal applicator if package has been damaged.
- Store at ambient temperature, do not expose to temperatures above to 55°C.

**Package**

- 1 vacuum syringe.
- 1 corneal iontophoresis applicator for veterinary use.



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**Mode of use**

Required material for the procedure

- **Riboflavin 0,1%**, sterile.
- A **sterile hypodermic needle** as a return electrode (min. diam. 25G – min. length 5/8 inches or 16 mm), to be adapted with the size of the animal (not supplied).
- An **empty syringe Luer-lock**, sterile (not supplied).
- A **blepharostat** (not supplied).
- **Current generator**, I-ON CXL<sup>®</sup> for veterinary use.
- **Ultraviolet light emitting source** for ophthalmic use (UV-A; 370nm) with a power from 3mW/cm<sup>2</sup> to 30mW/cm<sup>2</sup>, to deliver a total amount of 5,4 J/cm<sup>2</sup>, with a beam diameter of 8 mm.

**Patient Preparation**

1. The patient shall be put under general anesthesia, and positioned so that the eye to be treated is positioned horizontally.
2. Position the blepharostat in order to keep the lids open.

**Warning :** The absorption spectrum of Riboflavin and fluorescein are very close, so do not use fluorescein before treatment. Also, certain antibiotics may compete with Riboflavin. When in doubt, stop topical antibiotics 24 hours before treatment.

**Electrodes preparation**

3. Insert the hypodermic needle subcutaneously at the temporal palpebral canthus or in the neck.
4. Open the corneal iontophoresis applicator package.
5. Connect the vacuum syringe (10) on the female Luer lock (4) and verify that the clamp (3) is open.
6. Make sure the current generator ION-CXL<sup>®</sup> is switched off.
7. Connect the current generator I-ON CXL<sup>®</sup> with the applicator at (9) and connect the current generator with the return electrode (hypodermic needle) thanks to the crocodile clip. (Refer to the instructions supplied with the generator for further details).
8. Position the applicator on the cornea (part 1) in contact with the ocular surface) taking care to recover the area to be treated. The applicator must not extend beyond the cornea.
9. Press gently on the eye with the corneal applicator and perform a sufficient aspiration with the syringe. Then close the clamp (3).
10. Verify that the applicator is fixed well on the patient eye; if not, repeat points 8 to 10.
11. Disconnect and remove the vacuum syringe.
12. Using the sterile syringe, fill the corneal applicator reservoir (5) with RiboVet until the level is above the mesh electrode (6). Reservoir filling can be performed either by the riboflavin tube (7) or by the top of the reservoir. In both cases, riboflavin syringe shall be connected to the yellow Luer connector during the procedure in order to avoid leakage through the tube. The mesh electrode should be completely immersed during the whole procedure, to obtain a proper electrical contact.

**Treatment Procedure**

13. Turn on the current generator, choose 1 mA and press START (refer to the instructions supplied with the generator for further details).
14. The procedure should last 5 minutes. Avoid touching the applicator during the procedure. Bubbles could appear under the grid during the procedure: this is the proof that current is flowing. However this event is not a sign of temperature rise.

**DO NOT** remove the electrode before the end of the treatment.

15. If the patient can't stand 1 mA current (it rarely happens), switch the current to 0,5 mA. The generator automatically adapts the time left until achieving the total current emission of 5 mA.min.
16. **Draining:** at the end of the treatment, remove the solution from the reservoir (5) through the tube (7).
17. **Open** the clamp (3) to let air enter in the vacuum ring (1) and remove the applicator from the eye. Disconnect the current generator from applicator and from the hypodermic needle. Take off the hypodermic needle from the patient.

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## RIBOVET (Riboflavin 0,1%)

Hypotonic ophthalmic solution specially designed for transepithelial administration by iontophoresis in the treatment of infectious keratitis by corneal collagen cross-linking in animals.

**Description**

RiboVet is an ophthalmic solution containing hypotonic Riboflavin (0,1%), specifically formulated to allow quick passage of the Riboflavin into the corneal stroma through the intact epithelium, by means of a low intensity electric field applied topically (iontophoresis). RiboVet provides a barrier against the penetration of UV-A rays over the corneal stroma, thereby preserving the delicate internal structures of the eye (corneal endothelium, lens and retina) from damage caused by radiation. RiboVet is able to reduce up to 95% the intensity of the UV energy that reaches the deep layers of the cornea.

**Indications**

The soaking of cornea with RiboVet, in association with ophthalmic UV-A radiations, is indicated for the treatment of infectious keratitis and corneal melting.

In particular, the treatment is indicated in the following conditions:

- For infectious keratitis not responding to antimicrobial therapy.
- For severe infectious keratitis associated with corneal melting, to avoid emergency keratoplasty.

The treatment (UV-A + Riboflavin) is intended to cure infectious keratitis. The treatment can manage the infection and slow down the ulceration process before to perform keratoplasty. The treatment can stop the melting process. The treatment dose not exclude the possible need of keratoplasty in the future.

**Mode of use**

During the imbibition phase, instil RiboVet into the reservoir of the corneal applicator using a sterile syringe, until total covering of the mesh electrode.

**Composition**

Riboflavin Sodium Phosphate, Sodium edetate, Tromethamine, Sodium dihydrogen phosphate dehydrate, sodium phosphate dibasic dehydrate, purified water.

**Contraindications**

The product is contraindicated only in case of known hypersensitivity to components or other substances closely related from a chemical standpoint.

**Side effects**

There are no known systemic side effects or on the structures of the eye surface.

**Precautions**

- Keep the product away from light.
- The product in its bottle is sterile.
- Do not use the product after one hour from its intake from the bottle.
- Each bottle should be used for only one patient.
- Do not use the product after the expiration date indicated on the packaging.
- Do not store above 25°C.
- The product is intended for external ophthalmic use and must be used by veterinary staff only.

**Package**

1 vial containing 1,5 ml of solution.



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