

# REPEATER SPRAY

"Repeater" is a Medical Device for ophthalmic application based on a sterile, preservative-free, light viscosity aqueous solution, that contains elements which are naturally present in the ocular tissues and tear film.

"Repeater" is able to perform a protective, moisturizing and humectant action and therefore facilitates the process of re-epithelialization of the whole ocular surface (cornea and conjunctiva) due to the presence of high and low molecular weight hyaluronic acid.

The combined use of two different molecular weights of sodium hyaluronate results in a slight viscosity, a prolonged lubricating action on the eyes and a decrease in eye irritation.

"Repeater" increasing the volume and helping the functionality of the tear film favors a balanced ocular microenvironment.

The product must be used according to the instructions given in this information leaflet in order to avoid problems deriving from improper use.

## INTENDED USE

### DRY EYE

"Repeater" is indicated for the relief of moderate dry eye symptoms due to both extrinsic and intrinsic causes, such as:

- Unfavorable environment and climate conditions, such as the use of air conditioning (in the car, office, at home), strong wind, air pollution and when the climate is very hot.
- Chronic topical therapy with eye drops containing preservatives.
- Incorrect use of contact lenses, of any kinds, worn for long time during the day.
- Dry eye due to allergies, conjunctivitis, vitamin A deficiency.
- Anatomical eyelid alteration (incongruity eyelid-bulb, abnormal eyelid opening, abnormal blinking).
- Ocular pathology due to abnormal tear film lipid composition, such as blepharitis.
- Insufficient production of the lipid layer of the tear film due to Meibomian gland dysfunction.
- Inefficient blinking due to, for example, prolonged use of the computer or prolonged driving.
- State of menopause or post-menopause.

### SURGERY

"Repeater" is also indicated after surgery, and in particular refractive surgery, such as photorefractive keratectomy (PRK or excimer laser ablation) as it assists the physiological process

of ocular repair and re-epithelisation (during which the collagen synthesis necessary for the closure of the lesion occurs) as

- Contributes to an adequate degree of lubrication avoiding the rubbing of the eyelid during blinking, which would cause further irritation of the ocular epithelium and state of algia.
- Contrasts the dry eye condition (derived from the intervention itself or from the commonly prescribed drug therapy) thanks to the humectant and moisturizing action of hyaluronic acid
- It performs a marked antioxidant action (thanks to the triterpenes and flavonoids contained in the extract of centella asiatica, as well as Vitamin E) with capture of free radicals, thus protecting the damaged tissues
- Rebalances the ocular microenvironment compromised by the intervention, replenishing the tear film with substances physiologically present in it.

### CONTACT LENSES

"Repeater" is indicated for use with both soft and RPG contact lenses; more specifically:

- To cushion lenses: nebulize the product on the inner side of the lens prior to application on the eye; this will protect the corneal surface.
- With the lenses on the eye nebulize the product and blink a few times to make it more comfortable and relieve from dry eye. This also improves the wetting and hydration of the conjunctiva, minimizing the damages due to friction while blinking and in case of conjunctival tissue abrasions helps quicker healing.
- After lenses removal, nebulization of the product relieves from ocular fatigue due to long-time wearing moreover, "Repeater" contributes to repair the epithelial exfoliation which is the direct consequence of contact lenses use.

"Repeater" is indicated for frequent and prolonged use. Can be used during the day or alternatively before bed (night use).

### **COMPOSITION**

Hyaluronic acid sodium salt (high molecular weight) 0.02%, Hyaluronic acid sodium salt (low molecular weight) 0.02%, L-Glycine, Vitamin E TPGS, Extract of Centella Asiatica (L.) Urban, Polyvinylpyrrolidone, D-Mannitol, Sodium phosphate monobasic monohydrate, Sodium Phosphate dibasic dodecahydrate, Sodium Chloride, Water for injection.

### **INSTRUCTION FOR USE**

- Wash your hands thoroughly before using the product.
- Hold the bottle so that the finger that is used for dispensing (index or thumb) is well positioned on the dispenser and does not cover the spraying hole.
- Hold the bottle vertically and exert a firm pressure on the dispenser to nebulize 1-2 sprays of product in each eye, with the eyelids open or closed depending on your preference, unless otherwise prescribed. Nebulize from a distance of about 20/30 cm.
- On first use, before application of the product on the eye, deliver a few times in a vacuum until a regular nebulization of the product is observed.
- After the first opening, the contents can be reused within 3 months.

### **WARNINGS AND PRECAUTIONS**

- Product is for ophthalmic use only;
- Product is for single patient use;

- Do not use the product if container is damaged or not perfectly closed when you open it for the first time;
- Do not use if are visible particles and/or changes in the color of the solution;
- During application, do not touch eye or any other surface with the container's dispensing edge;
- Do not use the product after the expiry date indicated on the package;
- Do not use in case of known incompatibility towards any of the ingredients and/or Apiaceae plants;
- If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment;
- No interactions with drugs or other eye drops are reported; however, leave at least 15 minutes between administrations of any other eye drops;
- In case of side effects during use, interrupt the treatment and consult a doctor;
- Dispose of the product according to your local waste management regulations;
- Keep out of the reach and sight of children;
- Consult your doctor before you use this product if you are pregnant or breast-feeding;
- "Repeater" do not substitute any drug that may be prescribed by the doctor.
- For external use, do not swallow;
- Do not tamper with or damage the bottle and its mechanisms;
- It is necessary to report any serious incident occurred in relation to the device to the manufacturer and the Competent authority of the Member state in which you are established.

## SIDE EFFECTS

No undesirable side-effects are known so far.

## STORAGE CONDITIONS

Store below 30°C in a dry place away from heat and direct exposure to sunlight.  
Content must be used within 3 months after the first opening.

## PACKAGING

One bottle of 10 ml with spray dispenser of sterile solution preservative free.

## VALIDITY

See the expiry date reported on the box and on the container.



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