

# REPEATER

"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: place one drop 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 apply one or two drops to each eye 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, a few drops of product relieve 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) 0.120%, Hyaluronic acid sodium salt (low molecular weight) 0.050%, 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 and dry your hands thoroughly before use;
- Open the protective aluminium pouch;
- Detach the single dose container from the strip;
- Twist and remove the cap to break the seal;
- Place the cap taking care to put it on a clean surface;
- Gently press the single-dose container and instill 2 drops in each eye;
- After use immediately close the single-dose container: content must be used within 12 hours. To close it, you must first turn the cap over.

### WARNINGS AND PRECAUTIONS

- Product is for ophthalmic use only;
- Product is for single patient use;
- Do not use the product if the aluminum pouch is damaged or if the single dose is 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;
- In case of side effects during use, interrupt the treatment and consult a doctor;
- No interactions with drugs or other eye drops are reported; however, leave at least 15 minutes between administrations of any other eye drops;
- 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;
- 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 12 hours after the first opening.  
Store unused single doses in the aluminum pouch.

## PACKAGING

From 5 to 30 re-closable single dose of 0.5 ml

## VALIDITY

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



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