

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;
- Tear off the tamper-evident seal before the first administration;
- Remove the protective cap and open the bottle;
- Place the cap taking care to put it on a clean surface;
- Turn the bottle upside down and exert slight pressure on the bottle to instill 2 drops in each eye, unless otherwise prescribed;
- Wait a few seconds after each drop without squeezing the bottle. This will enable enough air to flow back into the system, otherwise it is more difficult to get the drops out;
- The gradual emptying of the bottle may be associated with the need to exert a higher pressure to allow the delivery of the product. This is due to the properties of the closure

system act to preserve the sterility and the chemical and physical characteristics of preservative free solutions. A small quantity of solution also always remains in the bottle;

- Shake off the remaining drop from the tip after use;
- After use close immediately the bottle with the cap;
- Do not put the protection cap back on when the container is still squeezed;
- Do not touch the applicator tip with anything, including your eye or your fingers;
- The content should be re-used within the next 3 months from the first opening.

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 try to tamper or disassemble the nozzle from the bottle;
- 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 of sterile solution preservative free.

VALIDITY

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



DT/01/DT/008



C.O.C. Farmaceutici S.r.l.

Via Modena, 15 - 40019

Sant'Agata Bolognese (BO) Italia

Last Revision: 02.01 del 10/2022



C.O.C. Farmaceutici srl

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41016 - Rovereto s/S - Novi di Modena (MO) ITALIA

Cap. Soc. € 1.200.000 I.V.
C.F. e Iscr. Reg.
Impr. di Bologna 03541870378
P.IVA IT 01603491208
R.E.A. Bologna N. 299432



Tubilux Pharma S.p.A.

Via Costarica, 20/22
00071 Pomezia (Roma)
ITALIA

cap. soc. € 472.500,00 I.V.
C.F. / P.IVA 05406661008
R.E.A. Roma N. 883476

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- After use close immediately the bottle with the cap;
- Do not put the protection cap back on when the container is still squeezed;
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