

# HYALUMILLA

"HYALUMILLA" is a sterile solution for ophthalmic use with physiological pH, dispensed in 10 ml multi dose bottle with a preservative free closure system.

The main action of the device is to lubricate and moisturize the ocular surface, thanks to sodium hyaluronate. "HYALUMILLA" is indicated in case of dry or irritated eyes.

Sodium hyaluronate contained in the solution provides to the product mucomimetic and viscoelastic properties such as to ensure adequate lubrication of the ocular surface, protecting it from friction caused by eye movements. For this reason, it soothes irritated and dry eyes. Furthermore, the polymer is able to retain water and simultaneously interact with the ocular epithelium. For this reason, the solution is able to maintain the ocular surface humidified, refreshes dry and irritated eyes and increases the stability of tear film that protects the surface from environmental agents.

The formula also contains: distilled waters of Ginkgo biloba, Indian Penny Wort, Blueberry and Fennel to ensure moisturising action, Sodium Chloride and two buffers agents (boric acid and sodium tetraborate decahydrate) to ensure a physiological solution.

"HYALUMILLA" can be used by contact lenses wearers. It is compatible with contact lenses.

## **INTENDED USE**

Repairing and protective ocular drops indicated to refreshing, soothing and lubricating action for dry eyes or in cases of irritation of the eye or the ocular mucosa due to:

- Environmental factors (air conditioned, excessive exposure to solar radiation, wind, smoke, pollution).
- Dryness of the eyes due to excessive fatigue caused by studying or working on the computer for lengthy periods, or dry eye syndrome.
- Ophthalmic stress following surface eye surgery.
- Wearing of contact lenses many hours a day.

#### COMPOSITION

Sodium hyaluronate 0,4%, Ginkgo biloba (*Ginkgo biloba*) distilled water, Blueberry (*Vaccinium myrtillus*) distilled water, Fennel (*Foeniculum vulgare*) distilled water, Indian Penny Wort (*Centella Asiatica*) distilled water, Boric acid, Sodium tetraborate decahydrate, Sodium chloride, Water for Injections.

#### **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;
- Press the container and instill 1/2 drops in each eye; no more than 10 doses (1-2 drops per eye) should be applied per day;
- 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 proprieties 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 product can be used up to 6 months after first opening.

## **WARNINGS AND PRECAUTIONS**

- The product contains the following CMR substances in concentrations above 0.1% w/w: boric acid and sodium tetraborate decahydrate. The product is not suitable for children, pregnant and breastfeeding women;
- 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;
- In case of side effects during use, interrupt the treatment and consult a doctor;
- Do not use in case of known incompatibility towards any of the components of the solution and/or Ericaceae plants and/or Apiaceae plants and/or Anacardiaceae plants and/or Poison Ivy and/or celery;
- 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;
- 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.

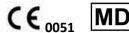
After the first opening the content must be used within 6 months.

## **PACKAGING**

One bottle of 10 ml of sterile solution preservative free.

#### **VALIDITY**

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









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