

# **BLUEMILLA 15ml**

BLUEMILLA is a sterile ophthalmic solution, with physiological pH, based on sodium hyaluronate, with benzalkonium chloride as preservative.

The main action of the device is to lubricate and moisturize the ocular surface, thanks to sodium hyaluronate. BLUEMILLA helps your eyes feel moisturized and refreshed.

BLUEMILLA is indicated to counteract dry eyes symptoms therefore it relieves redness, irritation and eye fatique.

The formula contains also sodium chloride and phosphate buffer to guarantee a physiological solution and distilled waters of Chamomile and Cornflower to ensure moisturizing action.

#### **INTENDED USE**

Eye drops indicated to counteract dry eye symptoms and relieve irritation, redness and eye fatigue due to environmental factors (air conditioning, excessive solar radiation, wind, smoke, pollution, sea water or swimming pool water), contact lens wear, driving long distances, long-term computer use.

#### COMPOSITION

Sodium hyaluronate 0.1%, distilled water of cornflower, distilled water of chamomile, sodium phosphate bibasic heptahydrate, sodium phosphate monobasic dihydrate, tween 80, benzalkonium chloride, sodium chloride, water for injections.

## **INSTRUCTION FOR USE**

- Wash and dry your hands thoroughly before use;
- Before using the product for the first time, firmly unscrew the protective cap to break the guarantee seal;
- Open the bottle by turning the protective cap anticlockwise;
- Remove the protective cap;
- Turn the bottle upside down and gently press the container to instill 2 or 3 drops into the eye;
- After use, close the container by turning the protective cap clockwise.

## WARNINGS AND PRECAUTIONS

• Due to benzalkonium chloride, do not use in case of eye diseases (e.g. glaucoma, Leber hereditary optic neuropathy);

- The product is intended for the use in adults and elderly. It is recommended to consult your doctor in case of use on children.
- Do not use the eye drops for longer than 28 days after first opening the bottle. Discard 28 days after opening, even if there is solution remaining;
- This product must not be used more than 3 times a day;
- Remove your contact lenses before applying this product and wait at least 15 minutes after using this eye drops before putting contact lenses back in;
- This product is for ophthalmic use only;
- This product is for single patient use;
- Do not use if the safety-seal on the cap of the bottle is broken;
- During application, do not touch eye or any other surface with the container's dispensing edge;
- Do not use after the expiry date shown on the carton or printed on the bottle;
- Do not use if you are allergic to any of the ingredients;
- Do not use if you are allergic to Asteraceae 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;
- For external use only, 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 at room temperature (15°C-25°C).

The product can be used for up to 28 days once opened.

#### **PACKAGING**

One 15 ml bottle.

## **VALIDITY**

Check the expiration date indicated on the carton. The expiry date indicated on the package refers to the product in intact packaging.









DT/01/DT/014



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

Via Modena, 15 - 40019

Sant'Agata Bolognese (BO) Italia

Distributor's address:

Last Revision: 01.01 del 02/2023



C.O.C. Farmaceutici srl

Via Modena, 15 40019 - S. Agata Bolognese (BO) ITALIA Via Chiesa Sud, 156 C/D/E/F/G 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