

BLUMILLA

"BLUMILLA" is a sterile, ophthalmic moisturizer and lubricant solution, with physiological pH, based on sodium hyaluronate and dispensed in single dose vials.

Sodium hyaluronate is used for its moisturizing and lubricating effect, which counteracts dry eyes and creates a film that protects the corneal epithelium from environmental agents. The formula contains also Sodium Chloride and phosphates buffers, sodium phosphate dibasic heptahydrate and sodium phosphate monobasic dihydrate to guarantee a physiological solution and distilled waters of Chamomile and Cornflower to ensure moisturizing action.

INTENDED USE

"BLUMILLA" is indicated for dry eyes or discomfort of the eye or ocular mucosa due to:

- environmental factors (air conditioning, excessive solar radiation, wind, smoke, pollution, sea water or swimming pool water);
- dry eye resulting from excessive fatigue due to long hours working on computers, studying or due to dry eye syndrome;
- use for many hours a day of contact lenses.

COMPOSITION

Sodium hyaluronate 0.1%, distilled water of cornflower, distilled water of chamomile, sodium phosphate bibasic hepta-hydrate, sodium phosphate monobasic di-hydrate, sodium chloride, water for injections. Preservative-free.

INSTRUCTION FOR USE

- Wash and dry your hands thoroughly before use;
- 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;
- Instill 2/3 drops in each eye by gently squeezing the single-dose container;
- After use immediately close the single-dose container: content must be used within 12 hours;
- "BLUMILLA" can also be used several times a day based on personal needs or a doctor's advice;
- "BLUMILLA" can be used with contact lenses.

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 in case of known incompatibility towards any of the ingredients and/or in case 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;
- Do not use the product after the expiry date indicated on the package;
- 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;
- 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).

Content must be used within 12 hours after the first opening.

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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MD

STERILE A

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DT/01/DT/001



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