

BLUE SHIELD

"BLUE SHIELD" is a medical device for ophthalmic use. It's a sterile, preservative-free, medium-viscosity, physiological and iso-osmotic, containing hyaluronic acid, rosmarinic acid and vitamin B12.

"BLUE SHIELD" mainly performs a moisturizing and lubricating action.

Hyaluronic acid is a biocompatible polymer and is naturally found in many human tissues. It gives to the product lubricant action thanks to its viscoelastic and water-retentive properties. In addition, it restores tears volume.

Rosmarinic Acid and Vitamin B12 are antioxidant substances that react with and neutralize free radicals. The antioxidant action takes place on the corneal surface.

"BLUE SHIELD" supports physiological and integrative antioxidant mechanisms and increases the aqueous component of the tear film, with the final effect of maintaining or restoring the eye-tissue trophism. It is therefore particularly suitable for dry eye, eye allergy or other eye discomfort caused by environmental or mechanical stress. It is also indicated to shield and protect from UV radiation and blue light.

INTENDED USE

ANTIOXIDANT ACTIVITY

"BLUE SHIELD" for the association of Rosmarinic Acid and Vitamin B12 carries out an antioxidant activity to counteract the action of free radicals (generated on the ocular surface after sun exposure) that with time damage both epithelium pigmented and photoreceptors inducing macular degeneration and causing crystalline opacification with onset of cataract.

Furthermore, thanks to its antioxidant action, "BLUE SHIELD" shields and protects the eyes from damages caused by UV radiation and BLUE LIGHT, both of natural (solar) and artificial origin such as PC, Tablet, Smartphone and TV screens.

PROLONGED USE AND CONTACT LENSES WEARERS

"BLUE SHIELD" is also indicated for frequent and prolonged use.

"BLUE SHIELD" can be used with daily contact lens: a little bit colour variation of the lenses, when the lenses are removed, does not affect optical properties.

COMPOSITION

Sodium hyaluronate 0.12%, Rosmarinic acid (extracted from *Coleus forskohlii*) 0.020%, Allantoin, hydroxypropylmethylcellulose, Glycerin, Vitamin B12 0.010%, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic dodecahydrate, 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;
- Press the container and instill 2 drops into 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 product can be used up to 3 months after 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;
- 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, 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 between 2°C and 25°C in a dry place, away from sources of heat and exposure to direct 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/007



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

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