

OPHTHALMIC SOLUTION based on extract of Perilla and hyaluronic acid 0.25%

CHARACTERISTICS

Sterile, protective, antioxidant, humectant and lubricant ophthalmic solution. **PERFLO DROPS[®]** is a Medical Device for ophthalmic application consisting of a sterile hypotonic saline solution with high biocompatibility, at slightly viscosity and physiological pH, preservative-free, with Perilla dry extract and Hyaluronic acid, packed in 0.5 ml single vials.

Perilla extract is obtained from both the seeds and the leaves of the plant. It contains polyphenols that inhibit the action of free radicals and act as their scavengers, with an antioxidant action.

The **hyaluronic acid** is a highly biocompatible polysaccharide polymer which has a great capacity for holding water molecules and shows a visco-elastic behavior which makes it an excellent moisturizer and lubricant.

INDICATIONS

Due to the specific qualitative and quantitative composition and particularly to the polyphenols contained in the Perilla extract, the **PERFLO DROPS[®]** formula can have an antioxidant action due to the effect of combating free radicals (such as superoxide radicals) and chelation of metals.

Thanks to its antioxidant and anti free radical properties, the device protects ocular tissues against the consequences of oxidative stress caused by unfavourable environmental factors (mechanical stress from contact lenses, sunlight, smoke, dust, air conditioning, computer radiation).

The **PERFLO DROPS[®]** formulation is also refreshing, moisturizing, lubricating and humectant.

Furthermore, due to the slight viscosity selected, the **PERFLO DROPS[®]** formulation has a diluting action that increases the volume of the lacrimal fluid and helps remove (through blinking) foreign bodies such as allergens, dust and mucoid thickening.

The **PERFLO DROPS[®]** protects the ocular tissues by assisting the physiological antioxidant mechanisms and supplementing the aqueous component of the tear film, thus favouring the maintaining or restoring of epithelial trophism. The **PERFLO DROPS[®]** is indicated for:

- relieve and contrast temporary feelings of discomfort of the eyes (redness, dryness) caused by unfavourable environmental conditions, such as air conditioning, dry or very hot climate
- relieve states of fatigue, such as lengthy periods of driving or studying, or use of computers and/or excessive exposure to light or prolonged use of contact lenses
- relieve the occasional feeling of dry eyes associated with blepharitis and assisting the removal of any secretions
- preventing states of allergic conjunctivitis

For users of contact lenses: using **PERFLO DROPS[®]** ophthalmic solution before wearing contact lens makes application easier, as it moisturizes the eyes; using the drops after application of the lenses makes them more comfortable to use and contrasting the sensation of dryness. The **PERFLO DROPS[®]** is suitable for frequent and prolonged use.

INSTRUCTIONS FOR USE

1. Open the protective foil pouch
2. Separate the single-dose vial from the bar of 5 units
3. Twist and snap off the cap of the vial
4. Gently press the single-dose vial and instill 2/3 drops per eye; for users of contact lenses: if desired, instill 1 or 2 drops directly on the lens and wear it immediately
5. After application, immediately close the vial with its cap and use the content left over within 12 hours
6. Store the unused vials in the original foil pouch until the contents of the packet are used up
7. The product is for single-patient use

COMPOSITION

Perilla dry extract (polyphenols \geq 2.5%) 0.1%, sodium hyaluronate 0.25%, sodium chloride, sodium phosphate dibasic anhydrous, sodium phosphate monobasic monohydrate, purified water q.s. at 100 ml.

PACKAGING

The box is composed of 2 foil pouches, each one containing a 5 vial single-dose bar: each vial is 0.5mL and re-closable.

WARNINGS

The product is for ophthalmic use only. Once opened, the container must be closed with the appropriate cap and the residual solution must be used within 12 hours from the opening. Do not use the product if the packaging is damaged or the bottle is not perfectly intact. Keep out of the reach of children. Carefully clean hands before opening the vial to administer the solution. Do not touch the eye or other surfaces with the nozzle of the vial during installation. Do not use the product in case of known incompatibility to even one single component of the formulation. If necessary, check with your optics for the compatibility of the eye drops with the contact lenses used. In case of disturbances during use, immediately suspend the treatment and contact a doctor. Any administration of ophthalmic drug/s should be at least 15 minutes after the instillation of these eye drops, especially if the products contain benzalkonium chloride, or other quaternary ammonium salts, to avoid the precipitation of hyaluronic acid. The administration of ophthalmic drugs concomitantly with these eye drops should be carried out under the supervision of a doctor who can assess the possible interactions. Do not use the product after the expiration date indicated on the package. Do not disperse the container in the environment after use. Keep in a dry place, away from sources of heat and exposure to direct sunlight, at a maximum temperature of 25°C.

VALIDITY

24 months.

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Last review date: Rev. 01 April 2015

MEDICAL DEVICE

