

## **IDROFLOG**

### **Ophthalmic solution**

#### **Composition**

Sodium hyaluronate 2 mg/ml; hydrocortisone sodium phosphate 10 µg/ml; trisodium citrate; sodium chloride; potassium chloride; magnesium chloride; sodium phosphate dibasic; sodium phosphate monobasic; water for injections.

#### **Box**

One box of IDROFLOG contains 15 vials of 0.5 ml.

#### **What IDROFLOG is and why it should be used**

IDROFLOG is an ophthalmic solution containing sodium hyaluronate which, thanks to its mucomimetic and pseudoplastic properties, is evenly distributed on the ocular surface forming a viscoelastic protective bandage. In this way, performing a mechanical action ("*barrier effect*"), IDROFLOG stabilises the tear film and reduces friction caused by eye movements and blinking; it protects the surface of the eye, encouraging repair processes after discomfort of the cells of the corneal epithelium due to hyosecretion of the tear film. In fact, if the glands that secrete the tear film reduce - due to different factors - their normal activity, the corneal surface is then exposed more strongly to external factors. The latter, in time, cause a malfunctioning of the corneal epithelial cells with associated risk of the onset of troublesome inflammatory processes. Applying the IDROFLOG bandage protects the corneal surface from exposure to external factors and, thanks to the ancillary action of Hydrocortisone Sodium Phosphate (low-dose, low anti-inflammatory power and short-term action cortisone agent), helps to prevent the risk of any recurrences of inflammation.

IDROFLOG must be used for a limited period of time and in any case under the direct control of your specialist doctor.

Finally, IDROFLOG, thanks to its special saline composition, restores and maintains at physiological levels the major ion concentrations, such as sodium, potassium and magnesium, essential for the health of the eye surface. The device does not contain preservatives.

#### **When it should be avoided**

Hypersensitivity to the components or other substances strictly related from the chemical perspective.

In concomitance with viral contaminations of the eye surface, keratitis ulcers, mycosis of the eye, purulent conjunctivitis, purulent and herpetic blepharitis, styes.

Generally contraindicated in pregnancy, during breastfeeding and for children.

#### **Driving vehicles or using machinery**

The product, due to its viscoelastic properties, may cause blurred vision at instillation. Wait for this effect to end before driving vehicles or using machinery.

#### **Precautions for use**

IDROFLOG is only for external use.

IDROFLOG should not be used immediately before the administration of medications for therapeutic purposes and for twenty minutes after the application of any pharmacological treatment topically.

If, during treatment, you notice a deterioration of your eye symptoms, contact your doctor immediately.

Prolonged use may cause problems: the total duration of the treatment should be determined by your eye doctor.

If an inflammation is already in process, your specialist will decide upon the appropriate anti-inflammatory treatment with a view to restoring the physiological conditions of the eye surface.

To reduce the risk of contamination during use, the aluminium bag should only be opened when the product is to be used immediately. Do not allow the tip of the vial to come into direct contact with the fingers, eye or any other surface.

### **How often and how long IDROFLOG should be used**

IDROFLOG should be dosed individually according to your condition and as recommended by your eye doctor. In general, instil 1-2 drops of the solution into the conjunctival sac of the eye to be treated, 2-4 times per day. The total treatment duration is 2-6 months but it must be specifically determined by your eye doctor and under his/her direct control anyway (a follow-up every 30-45 days is recommended).

### **How IDROFLOG is to be applied**

Detach a single vial from the strip. Remove the flap at the top by rotating it.

Instil 1-2 drops into the conjunctival sac, dropping them from above.

IDROFLOG may even be used when wearing contact lenses.

### **Adverse effects**

In rare cases slight blurring of the vision is observed upon instillation, which is due to the viscosity of the solution.

During instillation a slight burning feeling may occur. That sensation, however, will disappear.

Contact your eye doctor if the symptoms continue. Following the instructions contained in the explanatory leaflet reduces the risk of side effects.

### **Expiry and storage**

IDROFLOG should be stored at a temperature between 2°C and 25°C.

The product does not contain preservatives.

The product is for single use: after the first use, discard the vial even if it still contains some residual solution.

### **Caution**

Do not use IDROFLOG after the expiry date shown on the packaging. The expiry date refers to the product that is intact and correctly stored.

Keep out of the sight and reach of children.

IDROFLOG must be used after taking advice from your specialist doctor.

Manufacturer:

**ALFA INTES Industria Terapeutica Splendore S.r.l.**

Via Fratelli Bandiera, 26

80026 Casoria (Italy)

Rev. 00 dated 07/2018