Package Leaflet: Instructions for use

Lubristil® Gel

Transparent, sterile, preservative-free eye gel containing Sodium Hyaluronate and Xanthan Gum

Description

Each single-dose unit contains 1.5 mg Sodium Hyaluronate, 10 mg Xanthan Gum, Sodium Chloride, Potassium Chloride, Magnesium Chloride Hexahydrate, Calcium Chloride Dihydrate, Disodium Phosphate Dodecahydrate, Monobasic Sodium Phosphate Monohydrate, Sodium Citrate, Glycerol, Purified Water.
There are 20 single-dose units in each carton.

What is Lubristil® Gel and what is it used for?

Lubristil® Gel gives relief to the symptoms of ocular dryness of different origin.
Lubristil® Gel is also indicated for the medication of wounds and abrasions of the ocular surface caused by traumatic events and following surgery or associated with lachrymal film alterations.

Characteristics and mode of action:

Lubristil® Gel contains two natural polymers, sodium hyaluronate and xanthan gum. After instillation in the conjunctival sac, Lubristil® Gel mixes with tears and forms a lubricating, viscous and transparent layer which, reducing friction due to eye movements and blinking, alleviates the symptoms of ocular dryness due to environmental and climatic conditions such as pollen, dust, glare, pollution and computer monitor use.
In the same way, the product grants protection to the ocular surface during the healing process following wounds or abrasions.
The absence of preservative makes the product better tolerated.

Route of administration

Lubristil® Gel is only for topical ocular use.

STERILE A Sterility of Lubristil® Gel

Lubristil® Gel has been manufactured using aseptic processing techniques. It cannot be resterilised.

Precautions - Before you use Lubristil® Gel

Do not use Lubristil® Gel
- If you are allergic (sensitive) to any of the ingredients listed above.
- If the seal is broken or if the container is opened or damaged.

Each single-dose container must be used **immediately** after opening. Any residual product should **not** be used.
The single-dose containers must be used within 12 weeks from opening the aluminium pouch.

The administration of Lubristil® Gel to children or people with limited skills should be supervised by a responsible adult.

Using other medicines or medical devices for ocular use
Product interactions with the administration of other ophthalmic drugs are unknown. However, due to the physical properties of the gel, it is advised to not administer other drugs or medical devices for ocular use within 60 minutes after instillation of Lubristil® Gel.

Side effects
Transient and mild burning may occasionally occur. If the symptoms persist, it is advisable to consult your doctor.

COD. 1F155630G1

Contraindications:
Hypersensitivity to product components.

Administration - How to use Lubristil® Gel

Instil one drop of Lubristil® Gel in the conjunctival sac.
Unless otherwise directed by your ophthalmologist, it is possible to administer the product up to 4 times daily.

Figure 1

1. Wash your hands. Pull apart the single-dose container from the strip. Before use make sure that the single-dose container is intact. Shake the single-dose container at an angle until the Gel moves towards the tip (See Figure 1).

Figure 2

2. Hold the single-dose container from the lower part. Open a single-dose unit by twisting and pulling off the cap (see Figure 2).

Figure 3

3. Carefully pull down the lower eyelid to form a space between the eye and the eyelid (see Figure 3).

4. Gently squeeze a drop of Lubristil® Gel into the eye but do not touch the eye with the tip of the container (see Figure 4).

Figure 4

5. Close the eye for 30 seconds then open your eyes and blink a few times (see Figure 5).

Figure 5

6. Repeat these instructions for the other eye if required.

7. Wash your hands.

Disposal

Lubristil® Gel is preservative-free. Please dispose of each single-dose unit after use in an environmentally friendly way.

Storing Lubristil® Gel

The single-dose containers must be used within 12 weeks from opening the aluminium pouch.
Store below 30°C.

Use once and discard the single-dose unit.

Do not use after the expiry date printed on the box.

Keep out of the reach and sight of children.

Manufacturer:
Moorfields Eye Hospital NHS Foundation Trust trading as Moorfields Pharmaceuticals,
34 Nile Street, London, N1 7TP, United Kingdom.

Original Equipment Manufacturer:
S.I.F.I. S.p.A. – Via Ercole Patti, 36
95020 Lavinaio (Aci S. Antonio) – Catania – ITALY.

Last revision of this text: July 2011.
PCS-IFU2005

CE 0120

MOORFIELDS PHARMACEUTICALS

COD. 1F155630G1