Eyestil **GEL**

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Transparent, sterile, preservative-free eye gel
containing sodium hyaluronate 0.15 % and xanthan gum 1%

Indications
EYESTIL GEL gives relief to the symptoms of ocular dryness. It is intended to soothe symptoms of ocular discomfort due to wearing contact lenses.
EYESTIL GEL is also indicated for the medication of wounds and abrasions of the ocular surface caused by traumatic events and after ocular surgery.

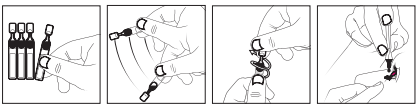
Composition
Sodium hyaluronate 0.15%, xanthan gum 1%, sodium chloride, potassium chloride, magnesium chloride hexahydrate, calcium chloride dihydrate, disodium phosphate dodecahydrate, monobasic sodium phosphate monohydrate, sodium citrate, glycerol, purified water.

Presentation
30 preservative-free single-dose vials containing 0.4 ml of gel.
1 package leaflet.

Characteristics and mechanism of action
EYESTIL GEL contains two natural polymers: sodium hyaluronate and xanthan gum. After instillation in the conjunctival sac, **EYESTIL GEL** mixes with tears and forms a lubricating, viscous and transparent layer, reducing friction due to eye movements and blinking.
EYESTIL GEL alleviates the symptoms of ocular dryness due to environmental and climatic conditions such as pollen, dust, glare, pollution, computer monitor use.
EYESTIL GEL also protects the eye surface during wound or abrasion healing processes.
The absence of preservative makes the product well tolerated.

Dosage and administration
Instil 1 drop of **EYESTIL GEL** in the conjunctival sac 4 times daily, unless instructed otherwise by physician.

Directions for use
Wash/sanitize your hands before use.
1. Make sure that single-dose container is intact.
2. Pull apart the single-dose container from the strip.
3. Hold the single-dose container from the lower part and shake it downwards.
4. Open the unit by twisting and pulling the cap.
5. During instillation of **EYESTIL GEL**, avoid touching the eye or any surface with the tip of the container.



Contraindications
Hypersensitivity to product components.

Precautions and warnings
Do not use **EYESTIL GEL** if the container is opened or damaged.
Avoid touching the eye or any surface with the tip of the opened container.
Each single-dose container should only be used immediately after opening. Any residual solution in the vial should not be used since **EYESTIL GEL** does not contain preservatives and the remaining product may become contaminated, increasing the risk of eye infections.
The single-dose containers must be used within 12 weeks after opening of the sachet.
Do not use **EYESTIL GEL** if it is not transparent.
Store below 30 °C.
Do not use **EYESTIL GEL** after the expiry date.
Do not dispose of the product in the environment after use. For the correct disposal of the product, please follow the national or local regulations.
The administration of **EYESTIL GEL** to children or people with limited skills should be supervised by a responsible adult.

Interactions with other drugs 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 not to administer other drugs or medical devices for ocular use within 60 minutes after the instillation of **EYESTIL GEL**.
The concomitant use of therapeutic contact lenses after photorefractive keratectomy (PRK) surgery resulted to be compatible with the use of the product.

However, the use of other kinds of contact lenses is advised only 60 minutes after the application of EYESTIL GEL.

Undesirable effects
Transient and mild burning may occur occasionally.

Notification of adverse reactions
Any adverse reactions should be reported to the local Vigilance Authorities or to:
SIFI S.p.A. - Via Ercole Patti, 36
95025 Aci Sant'Antonio (CT) Italy
e-mail: vigilance@sifigroup.com

FOR TOPICAL OCULAR USE ONLY
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Manufacturer
SIFI S.p.A. - Via Ercole Patti, 36
95025 Aci S. Antonio (CT) - ITALY

EYESTIL GEL is a sterile medical device.

Last revision of the text: February 2023

CE 0373

PATENT NUMBER: EP 1 358 883

Detailed and updated information on this medical device is available by scanning the QR code that appears in the instructions for use and the carton box with a smartphone. The same information is available at the following https://qr.sifigroup.com/1G809070/

Scan:

Simboli - Symboles - Symbols - Simbolos

	Fabbricante - Fabricant Manufacturer - Fabricante
CE 0373	Marchio CE e codice Organismo Notificato Marquage CE et code organisme notifié CE Mark and Notified Body Code Marcado CE y código del organismo notificado
STERILE A	Sterilizzato mediante processo aseptico sistema di barriera sterile singolo (vials) con imballaggio protettivo esterno (sacchetto) Stérilisé en utilisant une technique aseptique système de barrière stérile unique (flacons) avec emballage protecteur extérieur (sachet) Sterilized using aseptic processing technique – Sterilized by an aseptic process – single sterile barrier system (vials) with protective packaging outside (pouch) Esterilizado utilizando técnicas de procesado aséptico sistema de barrera estéril simple (envases) con embalaje protector exterior (bolsa)
LOT	Numero di lotto - Numéro de lot Batch code - Código de lote
	Mese ed anno di fabbricazione Mois et à l'année de fabrication. Month and year of manufacture Año y mes de la fabricación
	Utilizzare entro AAAA-MM Date de péremption AAAA-MM Use by YYYY-MM Fecha de caducidad AAAA-MM
	Non riutilizzare - Ne pas réutiliser Do not reuse - No reutilizar
30°C	Limite superiore di temperatura 30°C Limite supérieure de température 30°C Upper limit of temperature 30°C Límite superior de temperatura 30°C
	Non utilizzare se il contenitore è danneggiato Ne pas utiliser si le récipient est endommagé Do not use if package is damaged No utilizar si el envase está dañado
MD	Dispositivo medico Dispositif médical Medical device Producto sanitario
	Consultare le istruzioni per l'uso Consultez le mode d'emploi Consult instructions for use Consulte las instrucciones de uso
UDI	Identificativo unico del dispositivo Identifiant unique de l'appareil Unique device identifier Identificador único de producto