Why LIPITEAR[™] ?

- LIPITEAR[™] helps restore the proper microenvironment of the ocular surface which has been damaged due to traumas, ocular surgery, and instability of the lachrymal film or an increased tendency to evaporation
- LIPITEAR[™] is more effective than other products based on Hyaluronic acid in reducing the typical signs and symptons (pain/burning sensation, blurred vision, feeling of foreign body, photophobia and lacrimation) in patients suffering from dry eye⁴
- LIPITEAR[™] supports the physiological process of re-epithelization in terms of the rapidity and quality of the newly formed corneal epithelium⁵ by restoring a healthy microenvironment and reducing microtraumas caused by blinking

Indication of Use

LIPITEAR is intended for the following indications:

- Post-operative management of ocular surgeries (e.g. refractive surgery, cataract surgery, corneal transplant)
- Traumatic and spontaneous corneal erosions
- Dry eye syndrome



IOPtima

Special Precautions and Warnings

Do not use in case of specific hypersensitivity towards any of the constituents.

In case of blurred vision, perform each activity only after resolution of any transient blurred vision that may occur immediately after application of the product. Ask your doctor if the symptoms persist or get worse.

Rare cases of ocular irritation are possible after product instillation; in case of compared pain or visual reddening or visual disturbances interrupt the use of the solution.

As for all ocular products there is the risk of blurred vision for some minutes after the instillation. Do not drive or use dangerous machines until the vision is normal.

Do not swallow the solution.

Keep out of the reach of children.

Do not instill LIPITEAR[™] into the eye at the same time as other substances as the effect of these may be altered. Wait at least 15 minutes for the instillation of two different eye drops.

Do not use the solution after the expiry date. The expiry date shown on the package applies to the product kept refrigerated (2°-8°C). Where not refrigerated (kept at temperature not exceeding 25°C), the product should be used within 60 days.

Do not freeze.

Do not use if the package is damaged.

Bibliography

- 1. Rolando M., Calabria G. Superficie oculare e sostituti lacrimali. 1994, SAGEP editrice Genova. page 15
- 2. Hom M. M., Simmons P. A. Dry Eye: A Look at the R., De Gregorio F. Effects of an ophthalmic Numbers, October 2003, Optometric Management (http://www.optometricmanagement.com/ articleviewer.aspx?articleID=70859)
- 3. Solomon A., Kerry D., et al. Refractive surgery

- survey 2001. Journal of Cataract & Refractive Surgery 28.2 (2002): 346-355
- phospholipid microemulsion on the reto photorephractive keratectomy (PRK).Preliminary results. ISOPT 6th , Berlin, 2006 Medimonds S.r.l. ed. pp 97-102. Aragona P., Rolando M., Bonini S.,

LIPITEAR

OPtima | For more information please visit: www.lipitear.com

The product does not contain preservatives. Thus, after the container has been opened and the product used, the residual microemulsion, if any, should be disposed of to prevent any risk of ocular infection.

The unidose containers should be kept in the aluminium bag, away from light.

LIPITEAR[™] is a patented formulation by IOPtima Ltd.

CE 0123

Manufacturer: Tubilux Pharma SpA, Via Costarica, 20/22 - 00071 Pomezia (RM), Italy

Barozzi C., Falchetti R., De Gregorio F. Efficacy and safety of an ophthalmic microemulsion Lipimix in patients suffering from Dry Eye: single masked 4. Caporossi A., Rolando M., Barozzi C., Falchetti randomised clinical trial. ISOPT 6th, Berlin, 2006 Medimonds S.r.l. ed. pp 81-86

epithelisation process in patients who underwent **5.** Solomon A., Savion N. Enhanced corneal epithelium healing by Lipimix treatment. Poster and abstract presented at the ISOPT 7th 2008, Budapest, Hungary





 $\mathbf{LIPITE}\mathbf{A}\mathbf{R}^{\mathsf{M}}$ Phospholipid microemulsion for ophthalmic use





REFRESH. RENEW. RELIEVE.

IOPtima

Ocular Surface Disorder

The tear film plays a key role in the physiological repairing process. Its three constituting layers (aqueous, lipid and mucin layer) must function properly to ensure adequate production of tears in order to avoid symptoms of ocular surface disorder.

"Any alteration in one of these structures can cause a chain reaction involving all the other ocular surface components."¹



Irritation can occur when not enough tears are produced to keep the eye comfortably lubricated or when the eye does not produce an adequate amount of the tear film components. In general, dry eye disease, is among the most frequently established diagnoses in ophthalmology. Estimations reach up to 60 million affected people worldwide.² Additionally, photorefractive keratectomy and laser in situ keratomileusis can induce or exacerbate dry eye after surgery.³

Hence, in the treatment of ocular surface disorders, the therapeutic goal is to:

- Support repairing process
- Alleviate symptoms



Tear Film Reconstitution and Re-Epithelization

LIPITEAR[™] is a unidose ophthalmic microemulsion, preservative free. It is a medical device, marketed in Europe as CE Mark (Class IIa, rule 5)



LIPITEAR[™] helps reconstitute the physiological tear film.

The oil component restores the outer lipid layer of the tear film, lubricates the eye surface and prevents evaporation of the aqueous tear film component.

Altogether, **LIPITEAR**[™] provides long lasting reconstituted tear film that forms suitable physiological conditions for the natural corneal epithelium regeneration-healing process to occur.

ONCE DAMAGED...



EYE'm FEELING RENEWED

LIPITEARTM - Mechanism of Action

• **LIPITEAR™** consists of Phospholipids and Medium-Chain Triglycerides (MCTs) which imitate the natural tear film and form an elastic lipid shield

Phospholipid Medium Chain Triglyceride Structure Polar Head Apolar Tail

- The **Phospholipids** stabilize the tear film, anchor the lipid phase to the underlying aqueous phase and maintain the lipid layer organized in an orderly and elastic manner
- The **Triglycerides** reconstitute the physiological lipid shield, which controls evaporation of tear film, cornea surface lubrication and optical properties



