



7773690PT05/2A

EN  
INSTRUCTIONS FOR USE  
**THEALIPID®**  
Phospholipid microemulsion for  
ophthalmic use  
Multi dose 10 ml bottle

### 1. DESCRIPTION

**THEALIPID** is a microemulsion formed by an aqueous phase and a lipid phase. The main components of the lipid phase are the physiological constituents of the lachrymal fluid (phospholipids and medium-chain triglycerides). The submicroscopic lipid particles dispersed in the microemulsion protect the ocular surface by forming a thin hydrophobic barrier very similar to the lipid layer naturally contained in the lachrymal film.

### 2. INDICATIONS

**THEALIPID**, phospholipid microemulsion for ophthalmic use, is indicated for reducing dry eye symptoms in patients with an increased tendency to evaporation or instability of the lachrymal film, in patients submitted to refractive or other ocular surgery, with ocular traumas or prolonged exposure to video terminals.

### 3. CONTRAINDICATION

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

### 4. COMPOSITION

Soybean phospholipids, medium-chain triglycerides (MCT), soybean oil, glycerine, disodium edetate,  $\alpha$ -tocopherol and purified water.

### 5. DOSAGE

Instil 1 or 2 drops as needed or according to your specialist's advice.

### 6. DIRECTIONS FOR USE

Wash and rinse your hands thoroughly.



Remove the tamper-evident seal.



Remove the protective cap. Make sure that the tip of the bottle does not touch your fingers.



Lean your head back slightly, pull your lower eyelid down slightly with a finger of your free hand and hold the bottle vertically above your eye with the nozzle pointing downwards. Then gently squeeze the bottle to apply one or two drops into each eye, or according to your eye specialist's advice.

Avoid contact of the top of the bottle with your eye or fingers to prevent any possible contamination of the solution.



Replace the protective cap after use.

### 7. SIDE EFFECTS

- Transient blurred vision may occur when the drop is instilled. Wait until this clears before resuming normal activities and do not drive or use dangerous machinery until normal vision is resumed. Ask your doctor if symptoms persist or get worse.
- Cases of ocular irritation are possible after product instillation; if you experience pain, visual disturbances or reddening of the eye, stop using **THEALIPID** and consult your doctor.
- Inflammation, infection and allergy may occur when using this product.
- Corneal abrasion or ulcer could be observed in case of mishandling of the device.
- If you note any side effects or unusual sensations after using this product, please contact a healthcare professional and report the information to the local distributor, to the manufacturer or to your local Health Authority (see contacts at the end of the instructions for use).

### 8. WARNINGS

- Do not use in case of specific hypersensitivity towards any of the constituents.
- 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 vision is normal. Ask the doctor if symptoms persist or get worse.
- 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.
- Cases of ocular irritation are possible after product instillation; in case of pain or visual reddening or visual disturbances interrupt the use of the solution and consult your doctor.
- Do not swallow the solution.
- Keep out of the reach of children.
- Do not instil the product 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 share the bottle between different people to prevent cross contamination.
- Do not use the solution after the expiry date.
- Do not use if the package is damaged.
- To avoid the risk of blurred vision, it is not recommended to use the product during contact lenses wearing.

## 9. STORAGE CONDITIONS

- Store the product between 2°C - 25°C.
- Do not freeze.
- Do not use the product after the expiry date.
- After the bottle has been opened, the product must be used within 90 days. Any residual product must be disposed of.

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

**CE** 0123

THEALIPID® is a registered trademark of Laboratoires Théa. ©2021, Laboratoires Théa. All rights reserved.

**Date of last revision of the text:  
November 2022**

UK



THEA Pharmaceuticals Ltd,  
MED IC5, Innovation Way,  
Keele University Science and  
Innovation Park, Keele,  
Newcastle Under Lyme,  
Staffordshire, ST5 5NT  
www.thea-pharmaceuticals.co.uk  
0345 521 1290

### Health authority:

Medicines and Healthcare products  
Regulatory Agency, 10 South Colonnade,  
London, E14 4PU  
020 3080 6000













IE



Thea Pharma Ltd,  
Golden Mile Industrial Park,  
Breaffy Road,  
Castlebar,  
Co Mayo F23D299  
0 94 92 50290

### Health authority:

Health Products Regulatory Authority,  
Kevin O'Malley House, Earlsfort Centre,  
Earlsfort Terrace, Dublin 2, D02 XP77  
1 676 4971

 Manufacturer	 Consult instructions for use
 Batch number	 Single patient - Multiple use
 Medical Device	 Do not use if package is damaged
 Use-by date	 Date of manufacture
 Temperature limit	 Sterilized using aseptic processing techniques
 Keep out of the reach of children	 Distributor