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!! Customer approval !!	<p>This printing proof represents exactly the way the PI will be printed. This means that by putting your signature on it, you fully accept its design, texts and that anything comply on a regulatory point of view to your local requirements.</p> <p>Name: LAMB Tina ((UK) - Thea Pharmaceuticals Limited) Date: mandate for UNITED KINGDOM (GBR) Signature: 2021-06-11T17:10:59+02:00</p>	!! Manufacturer approval !!	<p>Your signature on this pdf means that you guarantee that technical aspects of this PI comply with the size of the PI, the cutting shapes, the margins, the codes and their positions, the reserved areas, the varnished areas, the braille and all the embossed elements and all the necessary marks in order to ensure that the finished product will look at what is shown below. You should not modify this pdf.</p> <p>Name: Date: Signature:</p>



This product is a medical device. Please read the instructions before use.

Keep this leaflet. You may need to read it again.

1. INDICATIONS

ZASPRAY is indicated to soothe, hydrate and lubricate dry eyes, especially associated with allergy.

ZASPRAY relieves itchy, dry, irritated and red eyes. Ocular use only.

2. CONTRAINDICATIONS

Do not inject and do not swallow.

Do not use **ZASPRAY** if you are allergic to any of its ingredients (see Device description).

3. DEVICE DESCRIPTION

ZASPRAY is a lubricating and soothing eye spray containing a liposomal solution based on PER-LIP® complex (liposome 4% + perilla seed extract 0.5%), sodium hyaluronate, boric acid, sodium tetraborate decahydrate, peg 300, disodium EDTA dihydrate, sodium chloride and water.

ZASPRAY is sterile and preservative-free, delivered in a 10 ml bottle equipped with the innovative APTAR® PLUS (multi-dose spray with tip seal technology) by APTAR®, which avoids the need for preservatives and prevents bacterial contamination over the duration of treatment. The absence of preservatives allows the protection of ocular tissues and also causes no reactions to users who are sensitive to preservatives.

ZASPRAY is a pleasant and easy-to-use alternative for people who find using eye drops difficult.

4. BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

ZASPRAY relieves itchy, dry, irritated and red eyes:

- providing freshness,
- soothing symptoms of irritated eyes,
- preventing dehydration of the surface of the eye,
- limiting water evaporation from the surface of the eye,
- restoring the natural balance of the eye surface and stabilising the tear film, protecting from environmental stress such as allergens, air conditioning, wind, dust, pollution and by eye strain due to bad lighting, prolonged use of contact lenses or long hours working in front of a computer.

ZASPRAY can be used in addition to antihistamines.

ZASPRAY is well tolerated on the eye surface.

Sodium hyaluronate is naturally found in the eye. It improves the tear film stability and keeps the ocular surface lubricated, hydrated and protected.

The spray delivers liposomes (the oily component called phospholipid) to the eye, helping to repair the lipid layer, thereby addressing the lipid instability that causes dry eyes, easing the irritation and discomfort of eye conditions.

Perilla is an antioxidant that helps counteract the accumulation of oxidative stress.

The combined action of PER-LIP® complex (liposomes + perilla) and hyaluronic acid helps to restore and improve the tear film stability, keeping the eye surface more hydrated and lubricated.

5. GENERAL RECOMMENDATIONS FOR USE

Dosage: It is recommended to spray on closed eyelids once or twice every application, 3 to 4 times a day for 3 to 4 days consecutively.

Do not use for more than 30 consecutive days.

There is no particular training required to use **ZASPRAY**.

1. Wash hands thoroughly before use.
2. Remove contact lenses before using the spray.
3. Hold the bottle tightly with your thumb or forefinger on the nozzle and pay attention not to cover the

nozzle hole.

- Hold the bottle approximately 10 cm from the eye.
- Apply onto a closed eye, putting firm pressure on the nozzle to allow a full spray to release.
- Repeat on the other eye if necessary.

6. CAUTIONS FOR USE

Multi-use spray for use by one person only.

Do not share bottles between different people to prevent cross contamination.

Check the packaging is intact before first using this product.

To avoid contamination, do not touch the nozzle with anything.

You must contact a healthcare professional if your symptoms get worse or do not improve.

7. WARNINGS

Keep out of the sight and reach of children.

In case of eye irritation, stop using the product and contact your doctor.

If you notice any side effects or unusual sensations after using this product, please contact a healthcare professional and report the information to the local distributor or to the manufacturer (see contacts at the end of the instructions for use).

8. STORAGE AND DISPOSAL CONDITIONS

Store the spray away from heat sources, in a dry place at a temperature between 9°C and 25°C.

Do not use after the expiry date, which is marked on the bottle and on the outer box.

The expiry date refers to the last day of that month as long as the packaging is intact, and it has been stored correctly.

The product can be used until 90 days after first opening. After this time, discard any leftover product responsibly and in accordance with local guidance.

Date of issue and version of the instructions for use: 04/2021

Manufacturer:

 NTC S.r.l., Via Luigi Razza, 3
20124 Milano
Italy

 0426

GB Distributor: 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

IE Distributor: THEA Pamex Ltd, 14 Moneen Business Park, Castlebar, Co. Mayo - 0 94 92 50290

Per-Lip®, registered trademark of NTC.

9. MEANING OF THE PICTOGRAMS ON THE PACKAGING

 Manufacturer	 Consult instruction for use
 Batch number	 Single patient - Multiple use
 Medical Device	 Do not use if package is damaged
 Use-by date	 Caution
 Temperature limits	 Sterilized using aseptic processing techniques
 Dispose of the product in accordance with local requirements	