Thealoz® Duo Gel

This product is a medical device. Please read the instructions before use.
Keep this leaflet. You may need to read it again.

INDICATIONS
THEALOZ DUO GEL is indicated to protect, hydrate and lubricate the surface of your eyes, for treatment of moderate to severe dry eye syndrome.
For ocular use only.

SUITABLE FOR
- Adults,
- Children: Parents or carers should administer the product,
- Pregnant or breastfeeding women based on current knowledge.

CONTRAINDICATIONS
Do not inject and do not swallow.
Do not use THEALOZ DUO GEL if you are allergic to any of its ingredients (see Device description).

DEVICE DESCRIPTION
THEALOZ DUO GEL is a gel containing trehalose (3%), sodium hyaluronate (0.15%), carbomer (Carbopol 974P, 0.25%), sorbitol, sodium hydroxide and water for injections.
THEALOZ DUO GEL is a sterile, phosphate-free, hypotonic and pH neutral fluid gel.

THEALOZ DUO GEL is gentle for eyes because it is preservative-free. Avoiding chemical preservatives is beneficial for the eye's surface long term and eliminates reactions amongst people who are sensitive to preservatives.

BENEFIT, PERFORMANCE AND MECHANISM OF ACTION
THEALOZ DUO GEL is recommended if you have discomfort, stinging, foreign body sensations or irritation of your eye due to moderate or severe ocular dryness. These symptoms can be caused by factors such as wind, smoke, pollution, dust, sunny or cold conditions, dry heat, air conditioning, plane journeys, long hours working in front of a computer screen and also by eye surgery such as refractive and cataract surgery.

THEALOZ DUO GEL provides comfort to the eyes, to relieve the symptoms of dry eyes all day long as described above.

The main ingredients of THEALOZ DUO GEL are trehalose, sodium hyaluronate and carbomer (Carbopol 974P): this unique combination of trehalose, sodium hyaluronate and carbomer in THEALOZ DUO GEL provides long-lasting protection, hydration and lubrication of the eye surface.
Trehalose is a natural substance found in many plants and animals, which need to survive in extreme conditions of temperature and dryness. It provides protective and hydrating properties.
Sodium hyaluronate, naturally found in the human eye, holds water to hydrate and lubricate the surface of the eye. It keeps the solution on the eye surface giving long lasting relief and improving the rate of healing.
Carbomer allows THEALOZ DUO GEL to stay on the eye surface longer, providing long-lasting relief of dry eye signs and symptoms.

GENERAL RECOMMENDATIONS FOR USE
Apply 1 drop to each eye, from 1 to 4 times a day.
As it is a gel, THEALOZ DUO GEL is particularly suitable for use in the evening, just before going to bed.

THEALOZ DUO GEL is easy to use.
If you wear contact lenses, you must remove them before using THEALOZ DUO GEL.
After use wait at least 30 minutes before putting your lenses back in.

Wash hands thoroughly before use.
Open the foil sachet and take one single-use vial off the strip.
Replace the rest of the strip back into the sachet.
Do not use any tool to open the vial.
Turn it upside down, gently shake and tap the vial until the gel comes down.
Open the vial by twisting the top tab off.
To avoid contamination, do not touch the tip of the vial with anything.
Squeeze until you see the drop.
Apply one drop in the pocket of the eyelid, while gently pulling the lower lid down and looking up. Close the eye gently after application.
Throw away the single-use vial, even if there is some gel left, do not keep it.



CAUTIONS FOR USE
Check the packaging is intact before first use: use only if the sachets and single-use vials are unopened.
To avoid contamination, do not touch the tip of the vial with anything.
Do not reuse the vial, because after you open it the contents are not protected from microbial contamination.
You must contact a healthcare professional if your symptoms get worse or do not improve.

WARNINGS
Keep out of the sight and reach of children.
After use, do not drive or use machines if your vision is blurred: wait for a few minutes until your vision clears.
Wait at least 15 minutes between using two different eye products. Use THEALOZ DUO GEL last.

SIDE EFFECTS

The followings side effects have been reported: sticky eyes, blurred vision, allergic reactions (such as hypersensitivity, swelling of eyelid, rash), eye discharge, rare possibility of eye irritation, eye pain and ocular redness.

When you use an eye gel, you might experience disturbing symptoms such as burning sensation, stinging sensation, foreign body sensation in the eye and blurred vision for a short time.

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, to the manufacturer or to your local Health Authority (see contacts at the end of the instructions for use).

STORAGE AND DISPOSAL CONDITIONS

Store between 8 °C and 30 °C.
Do not expose your product to direct sunlight or humidity.

Throw away the single-use vial immediately after use even if there is gel left in it.
Keep the unopened single-use vials in their sachet in order to protect them from light.
The unopened single-use vials can be used up to one month after first opening of the sachet.
Do not use after the expiry date which is marked on the single-use vials 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.
Dispose of the product responsibly and in accordance with local guidance (the single-use vial and the sachet should be disposed of as household waste, the outer carton and the leaflet are recyclable).

Date of issue and version of the instruction for use:
Ver. 10 04/2024

Manufacturer:
Laboratoires Théa
12 rue Louis Blériot
63017 Clermont-Ferrand Cedex 2 France
www.laboratoires-thea.com
« Contact us » section

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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
Tel.: 0345 521 1290

Health authority:
Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, London, E14 4PU
Tel.: 020 3080 6000

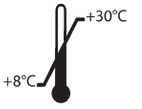
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Distributor:
THEA Pharma Ltd, Golden Mile Industrial Park, Breaffy Road, Castlebar, Co Mayo F23D299
Tel.: 0 94 92 50290

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

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MEANING OF THE PICTOGRAMS ON THE PACKAGING

	Manufacturer
LOT	Batch number
	Date of manufacture
	Use-by date
	Temperature limits
STERILE A	Sterilized using aseptic processing techniques
MD	Medical Device
	Consult instruction for use
	Single use
	Do not use if package is damaged
	Caution
	Keep away from sunlight
	Keep dry
REF	Catalogue number
UDI	Unique device identifier

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