

Please read these instructions for use carefully – they contain important information on how to use this product. If you have any questions, please ask your pharmacist, your doctor, eye care professional or contact us

BAUSCH + LOMB

ARTELAC[®]

PRO DEFENCE Revital Eyes Spray

Composition: Dexpanthenol (Provitamin B5) 0.5%, sacha inchi seed oil (*Plukenetia volubilis*) 0.5%, trehalose, glycerol and emulsifiers polyoxyethylene sorbitan monooleate and sorbitan monooleate in sterile and hypotonic trometamol/citrate emulsion.

Contains no preservatives, alcohol, phosphates, borates, mineral oil or materials of animal origin.

What is ARTELAC[®] Revital Eyes Spray?

ARTELAC[®] Revital Eyes Spray is a sterile ophthalmic solution that contains trehalose, glycerol, dexpanthenol (provitamin B5), as well as natural antioxidants and omega-fatty acids of sacha inchi seed oil. The advanced formulation has a high tolerability and is presented in a preservative free multi-dose system (PFMD), which is easy to use. Once opened, it can be used for 6 months.

What is the application of ARTELAC[®] Revital Eyes Spray?

Dry eyes are caused by a destabilisation of the natural tear film which can lead to damage to the eye surface and inflammation. This damage, left without proper protection by the tear film, causes uncomfortable sensations including itching, burning and grittiness of the eyes, and blurred vision. ARTELAC[®] Revital Eyes Spray is intended for treating and preventing symptoms and signs of dry eyes as well as protecting the eyelids and the skin around the eyes. Always apply the spray on closed eyelids.

When should you use ARTELAC[®] Revital Eyes Spray?

ARTELAC[®] Revital Eyes Spray contains sacha inchi seed oil that strengthens the tear film lipid layer to reduce evaporation. Trehalose, dexpanthenol, and glycerol bind water to help stabilise and lubricate the tear film. The mildly hypotonic (low-osmolar) solution also contains dexpanthenol (provitamin B5) and glycerol, as well as natural antioxidants and omega-fatty acids of sacha inchi seed oil.

They work together to protect the eye surface and the skin around the eyes from damage caused by drying, helping to support the natural healing process. Recovery of the eye surface reduces irritation and redness leaving the eyes feeling more comfortable.

ARTELAC[®] Revital Eyes Spray is suitable to be used only on closed eyes (eyelids). It is designed for the symptomatic relief of dry eyes such as inflammation, irritation and redness.

Dry eyes are caused by:

- External factors, like extensive computer use, air conditioning, heating, cigarette smoke, as well as windy outdoor environments and/or wearing contact lenses.
- Other factors, like certain drugs (such as the contraceptive pill, antihistamines, betablockers, antispasmodics and diuretics) or certain diseases that play a role in the development of ocular dryness.

Quick and easy application – spray on closed eyelids to protect and strengthen the natural tear film:

- Reduces inflammation & redness.
- Promotes healing of the eye surface.
- Provides protection to the skin around the eyes.
- Sacha inchi seed oil strengthens the natural tear film lipid layer to reduce evaporation of the tear fluid.
- Trehalose, dexpanthenol, and glycerol bind water to stabilise and lubricate the tear film.
- Dexpanthenol (provitamin B5), glycerol, and the natural antioxidants and omega-fatty acids of sacha inchi seed oil protect the ocular surface and the skin around the eyes from damage caused by drying and act to speed up the healing process.

How often and how long should you use Artelac[®] REVITAL EYES Spray?

Apply 1-2 sprays of ARTELAC[®] Revital Eyes Spray onto closed eyes (eyelids) as the need arises. You may use the spray several times a day as your symptoms require and during contact lens wear. There is no limit to the duration of use, ARTELAC[®] Revital Eyes Spray is very tolerable as it is free of any preservatives and alcohol. If you are using other personal care products in the eye area, let them settle for at least 10 minutes before applying the spray, or use the other product not earlier than 10 minutes after applying the spray. If you are using eye make-up, you may wish to apply the spray from a longer distance to avoid spreading, depending on the type of make-up.

When should you not use ARTELAC® Revital Eyes Spray?

- Do not use if you are sensitive to any of the ingredients. If in doubt, consult a healthcare professional.
- Do not use if the bottle is damaged.
- Do not use after expiry date printed on the bottle and carton box or after discard date (6 months after opening).

How to store ARTELAC® Revital Eyes Spray?

- Store at a temperature between +5 and +25°C, protect from direct sunlight.
- Do not use the product in the event it has frozen or it has been left in a hot place for a long time.
- The design of the bottle allows you to use ARTELAC® Revital Eyes Spray for 6 months after opening.

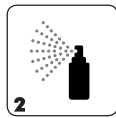
How to use ARTELAC® Revital Eyes Spray?

The pump mechanism of ARTELAC® Revital Eyes Spray allows the ophthalmic solution to be preservative free.

General note: The ophthalmic spray is designed to be used only on closed eyes (eyelids).



1. Before each use, remove the protective cap from the sprayer of the bottle by pulling upwards.



2. Before the first application, test the spraying mechanism a few times on your arm or in the air. There is a small step in the nozzle, press the nozzle head fully down to apply the spray. Hold the bottle 15-20 cm from the eyes, directing the nozzle towards the eye.



3. Close both eyes and then apply 1-2 sprays onto each eyelid and blink.



4. Put the protection cap back on the nozzle head.

Important information about using ARTELAC® Revital Eyes Spray:

- Do not use if the bottle is damaged.
- Do not touch the nozzle with eye or skin.
- Do not touch the tip of the nozzle with fingers.
- You may temporarily experience mild discomfort, if the spray is applied on an open eye.
- Do not use after expiry date printed on the bottle and carton box or after discard date (6 month after opening).
- Leave at least 10 minutes between applications of the spray and an ophthalmic medication.
- Keep out of reach and sight of children.
- Discard the empty bottle appropriately.
- Due to intentional overfill, a small volume of solution will remain in the bottle.
- This lipid microemulsion eye spray is a sterile CE marked registered medical device product.
- The manufacturer, Oy Finnsusp Ab, tel. +358 2 489110, and the Medicines and Healthcare products Regulatory Agency (MHRA) (UK) tel. +44 (0)203 080 7080 / Health Products Regulatory Authority (HPRA) (Ireland) tel. +353 1 6764971 must be notified of serious adverse events related to use of the product.

Presentation:

ARTELAC® Revital Eyes Spray is available as a 17ml eye spray.

Symbol



Title

Sterilised using aseptic processing techniques



Temperature limit



Can be used for 6 months after first opening



Consult Instructions for Use



Caution: Consult the "Instructions for Use" for important cautionary information such as warnings and precautions



Keep away from sunlight



Keep out of reach of children



Use-by date



Batch code



Medical device



Manufacturer



Date of manufacture

Manufactured for Bausch + Lomb by:



Oy Finnsusp Ab
Pääskykalliontie 5
21420 Lieto
Finland

www.artelac.co.uk



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Produced using proprietary DEMET™ microemulsion technology developed by Oy Finnsusp Ab.

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