OPTASE® Comfort Dry Eye Spray

What OPTASE[®] Comfort Dry Eye Spray is and what it is intended for

OPTASE® Comfort Dry Eye Spray is intended for dry, tired and strained eyes to relieve dryness and irritation in the eyes, eyelids and skin around the eyes.

Always apply the spray on closed eyelids only. The micro-emulsion contains sea buckthorn seed oil that slowly spreads on the tear film. The oil strengthens the tear lipid layer to protect the eyes from drying. Also, its natural antioxidant compounds protect the eye surface and the skin against cell damage and speed up their healing. Sodium Hyaluronate supports the water binding capacity of the tear film and lubricates the eyes; it also prevents cell damage and moisturizes the surrounding skin. Thanks to its special design, the bottle can be used in any position. Developed and manufactured in Finland, OPTASE® Comfort Dry Eye Spray is a sterile CE marked registered Medical Device product which contains no alcohol, no preservatives, and no ingredients of animal origin.

Instructions for use

Take off the protection cap. Before the first application, test the spraying mechanism a few times on your arm or in the air. Notice that there is a small step in the nozzle; to apply the spray, press the nozzle fully down. <u>Next, hold the bottle</u> <u>approximately 15–20 cm (6–8 inches) from the eyes.</u> <u>Close both eyes and then apply 1–2 sprays on the</u> <u>eyelids.</u>

Once you are ready, put the protection cap back on the nozzle head. You may use the spray several times a day and during contact lens wear. 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. Use within six (6) months from opening the bottle and by the expiry date indicated in the stamp on the bottle.



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Precautions and warnings

- Do not use if the bottle is damaged.
- To avoid contamination, do not touch the eye or skin with the tip of the nozzle.
- Do not touch the tip of the nozzle with fingers.
- Do not use after expiry date printed on the bottle and box or after discard date (6 months after opening).
- If the spray is applied on an open eye, you may temporarily experience mild discomfort
- Leave at least 10 minutes between applications of the spray and an ophthalmic medication.
- Keep out of reach and sight of children.
- Store at 5–25 °C, protect from direct sunshine and heat. Do not use the product in the event it has frozen or it has been stored in hot conditions for a long time.
- Discard the empty bottle appropriately. Due to intentional overfill, a small volume of the solution will remain in the bottle.
- Serious adverse events related to the use of the product must be reported to the manufacturer, Oy Finnsusp Ab, quality@piiloset.fi / +358 2 489110

Adverse events should also be reported as follows for the UK and Ireland: UK: Contact the MHRA: Email: aic@mhra.gov.uk, Tel: 0203 080 6000 IRE: Contact the HPRA: Email: devices@hpra.ie, Tel. +358 2 489110

Contraindications

Do not use if you are sensitive to any of the ingredients. If in doubt, consult a healthcare professional.

Composition

0.4% Sea buckthorn seed oil, sodium hyaluronate, glycerol, emulsifiers polyoxyethylene sorbitan monooleate and sorbitan monooleate in a sterile hypotonic trometamol/citrate buffer emulsion.

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