Microemulsion of polyunsaturated fatty acids and hydrating polymers

REMOGEN omega

DHA EPA

TRB CHEMEDICA

# **REMOGEN®OMEGA**

- acts on the three layers of the tear film
- is a hypotonic solution
- is indicated for the treatment of dry eye
- relieves symptoms in case of ocular irritation
- can be used even with contact lenses
- is preservative-free

**NOURISHES** the ocular surface with essential nutritive substances

- Omega-3 fatty acids reconstitute the lipid layer of the tear film
- Vitamin E reduces lipid oxidation and prevents free radical damages

**REBALANCES** the homeostasis of the tear film

**REDUCES** the hyperosmolarity related to dry eye disease

**HYDRATES** the ocular surface thanks to its hydrophilic components





# Microemulsion of polyunsaturated fatty acids and hydrating polymers

Sterile, preservative-free

# Instructions for use

REMOGEN® OMEGA - Microemulsion of polyunsaturated fatty acids and hydrating polymers.

Lubricant eye drops. Sterile, free from preservatives.

### Composition:

1 ml solution contains eicosapentaenoic acid (EPA) ethyl ester, docosahexaenoic acid (DHA) ethyl ester,  $\,\alpha$  -tocopheryl acetate (vitamin E), glycerol, polyacrylic acid, acrylates/alkyl acrylate crosspolymer, sodium hydroxide, disodium phosphate and water for injections. The microemulsion is hypotonic with a physiological pH value.

### Indications:

REMOGEN® OMEGA soothes, refreshes, lubricates, nourishes, hydrates and protects the ocular surface in all cases of qualitative and quantitative alterations and instability of the tear film that cause sensations of dryness, burning and discomfort of the eyes. In particular it can be used in case of symptoms and signs of dry eye and/or ocular surface damage, due to diseases such as superficial keratitis, Sjögren syndrome or primary dry eye syndrome. For lubrication of the eyes in case of sensation of dryness, burning and ocular fatigue and other minor complaints of no pathological significance induced, for example, by dust, smoke, dry heat, air conditioning, wind, cold, extended computer screen use, diseases of the immune system or the ingestion of drugs that decrease the tear secretion. Due to its protective action on the corneal and conjunctiva epithelia REMOGEN® OMEGA can be used in all cases of ocular irritation.

# Contra-Indications:

Individual hypersensitivity to any constituent of the product.

Do not use REMOGEN® OMEGA at the same time as any drug or other product applied to the eye since it may modify their effects. Wait for at least 15 minutes between instillation of two different products into the

# **Undesirable effects:**

On rare occasions transient disorders such as irritation of the conjunctiva, foreign body sensation, watery eyes or sticky eyelids, itching, redness, stinging or burning sensation of the eye as well as short-term blurred vision may occur.

# Dosage and administration:

Twist off the cap. Tilt the head backwards and position the tip of the container above the eye to be treated. Move the lower eyelid down with the forefinger of one hand. Press the container and one drop of REMOGEN® OMEGA will easily flow out. If not otherwise recommended, instill 1 or 2 drops of REMOGEN® OMEGA onto the eye as often as needed.

After blinking, the solution will disperse and form a transparent and long lasting coating on the surface of the eye. REMOGEN® OMEGA may also be used while wearing contact lenses (rigid or soft).

### Precautions:

Do not touch the tip of the opened container and do not touch the surface of the eye with the tip of the opened container. Any solution not used immediately after opening must be discarded. Otherwise the sterility is no longer guaranteed and this may be associated with a risk of infection. Do not use **REMOGEN® OMEGA** if the aluminium pouch or the containers are damaged. Store between 2 °C und 8 °C! Do not use **REMOGEN®** OMEGA after the expiry date indicated on the container and the folding box. This period refers to the product kept in the refrigerator (2 °C - 8 °C). Outside the refrigerator, the product has a shelf-life of 3 months if stored at a temperature below 25 °C and in its original packaging. Keep the product away from light, storing the single-dose containers in the aluminium pouch. If discomfort persists while using **REMOGEN® OMEGA** consult a physician. Keep out of reach of children.

# Characteristics and mode of action:

REMOGEN® OMEGA is a hypotonic microemulsion composed of a micrometric dispersion of lipid molecules (fatty acids and vitamin E, which are also physiological constituents of the tears) in an aqueous medium that contains hydrating and emollient substances such as glycerol, polyacrylic acid and acrylates/alkyl acrylate crosspolymer.

REMOGEN® OMEGA acts on the three layers of the tear film. In particular, the lipidic component of the microemulsion integrates with and regenerates the thin lipid layer of the natural tear film, reconstituting it physiologically and counteracting any hyperevaporation from the aqueous layer. The aqueous component of REMOGEN® OMEGA forms a hydrophilic film which adheres to the ocular surface, retains water and stabilizes the tear film, thus protecting the corneal and conjunctival

REMOGEN® OMEGA, a hypotonic microemulsion, also compensates for the hyperosmolarity of the tear film which is frequently associated with a non-physiological condition of the ocular surface. REMOGEN® OMEGA is free from surfactants and preservatives, substances that might damage the ocular surface.

# Presentation:

1 pouch of 5 single-dose containers of 0.25 ml 2 pouches of 5 single-dose containers of 0.25 ml 4 pouches of 5 single-dose containers of 0.25 ml

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