



Artelac® Rebalance

0,15% Hyaluronsäure, PEG 8000, essentielle Elektrolyte & Vitamin B₁₂

Dear User,

Thank you for choosing Artelac® Rebalance! It is a multi-component product ideal for providing enduring relief and protection for dry eye caused by chronic tear dysfunction. Artelac® Rebalance contains key components naturally found in the eye and tears and it helps supplement deficient tears and rebalance the tear film so that it can perform the functions and provide the protection it should. It acts to relieve a cascade of signs and symptoms caused by chronic tear dysfunction such as burning, tired, gritty, red and/or inflamed painful eyes. Available with an innovative disappearing preservative in a conventional eye drop bottle, Artelac® Rebalance is a multi-component solution for chronic tear dysfunction. It helps supplement natural tears providing instant lubrication and hydration to relieve your eyes while promoting a healthy ocular surface environment for enduring relief and protection.

- Artelac® Rebalance contains key components naturally found in the eye and tears, including sodium hyaluronate an effective moisturiser that binds water, nutrients and purifying ions (such as potassium, magnesium, sodium and calcium) to the surface of the eye for maximum hydration and relief.
- Artelac® Rebalance also contains Vitamin B₁₂, a known anti-oxidant, to help provide additional protection to the ocular surface. Vitamin B₁₂ also gives Artelac® Rebalance its rose colour, which quickly dissipates with blinking.
- Artelac® Rebalance is designed with dual polymers to increase the duration of relief
- Artelac® Rebalance is hypotonic and soothes the eye as it helps restore the physiological osmotic balance of the tear film and ocular surface
- Artelac® Rebalance is innovatively preserved with a preservative system that converts to water and salt, natural tear components, upon contact with the ocular surface.
- Artelac® Rebalance is easy to use, well tolerated, and safe.

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 or contact us.

Best wishes for you and your eyes from Bausch + Lomb!

Composition:

Artelac® Rebalance contains 0.15% hyaluronic acid, 0.5% polyethylene glycol 8000, potassium chloride, calcium chloride, magnesium chloride, sodium chloride, vitamin B₁₂, and sterile water. Oxyd is used as gentle preservative that converts to water and salt at the surface of the eye.

Presentation:

Artelac® Rebalance is available in 10ml eye drop bottle.

Intended use of Artelac® Rebalance:

Artelac® Rebalance is best suited for use to relieve and calm persistent dry eye symptoms due to chronic tear deficiency. Chronic tear deficiency can be caused by a number of factors including tear gland inflammation and dysfunction, eyelid and sensory deficiencies, and/or poor quality of tears.

When one or many of these factors compromise your tears a tear film imbalance results and a subsequent cascade of unpleasant signs and symptoms can result including: eye-surface inflammation, redness, the sensation of burning eyes, dryness, light sensitivity, the feeling of tired, gritty and painful eyes, that, if not treated, could lead to further inflammation and corneal damage. Also, certain drugs and procedures (such as the pill, antihistamines, betablockers, antispasmodics, diuretics; and LASIK or refractive surgery), certain diseases and preservatives in some eye drops can play an important role in the development of ocular dryness and corneal damage.

Due to the complex nature of tear dysfunction, there are limited treatments; however Artelac® Rebalance is designed with multiple components to provide long lasting relief from dry eye by supplementing the natural tear film with essential components for its proper function. It helps stop the cascade of dry eye symptoms, lubricate the eye, and protect the surface.

How often should you use Artelac® Rebalance?

Treatment for dry eye conditions requires an individual regime according to the severity and intensity of your symptoms. Instill one drop of Artelac® Rebalance into the eye 3 to 5 times daily, or more frequently if required.

Important information about using Artelac® Rebalance:

In rare cases this product can cause hypersensitive reactions such as local allergic reactions. Treatment should be discontinued in such cases.

Artelac® Rebalance is preserve-free at the surface of the eye due to an innovative preservative system (called Oxyd) that disappears into natural tear components (water and salt) upon contact with the surface of the eye.

Do not use Artelac® Rebalance after the expiry date.

Do not use if the bottle is damaged.

If you are using different eye preparations, wait approximately 15 minutes before using the second drops.

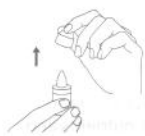
Artelac® Rebalance is compatible with all types of contact lenses, and can be instilled while wearing your contact lenses

Artelac® Rebalance is rose-coloured due to the presence of Vitamin B12 (cyanocobalamin), but it does not stain either clothing or contact lenses and any remaining light colouration disappears in the tears.

This is how you should use Artelac® Rebalance:

The illustrations show the simple and easy use of Artelac® Rebalance.

1. Remove the protective cap from the tip of the bottle before each use. Make sure that the tip of the bottle does not touch your fingers.



2. Lean your head back slightly and pull your lower eyelid down slightly with a finger of your free hand and hold the bottle vertically above your eye with the nozzle pointing downwards. Then gently squeeze the bottle to apply one drop.



Avoid contact of the tip of the bottle with your eye or your fingers to prevent any possible contamination of the solution.

3. Replace the cap on the bottle after each use.



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STERILE A

Sterilization method, aseptic



Storage of the medical device
in a temperature range of
+1°C to +25°C



Do not use Artelac® Rebalance
if the bottle is damaged.



The medical device can be used
for 2 months once opened.



Protect from light



Expiry date



Follow the instructions for use



Batch number

Additional information on Artelac® Rebalance

What role does the tear film play?

The tear film is comprised of three layers sitting on the front of your eye which provide essential nutrients to the surface of the eye, form a protective lubricating barrier between the eyelid and cornea, and ensure healthy function and clear vision.

The natural tear film is spread over the surface of the eye with every blink in order to provide nutrients, protect it from drying out, and to assist the healing of superficial injuries of the cornea and prevent further injury or damage. The innermost layer – the mucin layer helps bind moisture and tears to the eye. The middle and largest layer – the aqueous layer is a watery solution of nutrients and ions that help moisturise and protect the eye from infections. The outer-most layer – the lipid layer is a dense, oily layer that seals in moisture on the eye, allows for the free flow of the eyelid over the eye, and evens out the surface of the eye to provide sharper vision. It is a delicate symbiotic balance that ensures ocular surface health and comfort.

When the tear film balance is compromised by chronic tear dysfunction, insufficient or poor quality tears can create an imbalance in tear film layers and trigger a cascade of events (including eye-surface inflammation, redness) and symptoms (including irritation, burning, tiredness) that increasingly make the condition worse. Not only can it become more painful but it can damage the surface of your eye.

Chronic tear dysfunction is a complex disease for which there are no clear cures. However for most cases you can treat the symptoms of dry eye to become more comfortable as well as fortify/supplement your tears to help break the cascade of dry eye events and safeguard against inflammation and ocular damage.

How can Artelac® Rebalance help your eyes?

Artelac® Rebalance with the dual polymers of sodium hyaluronate and PEG 8000, sterile water with potassium, magnesium, calcium, sodium, and vitamin B12 lubricates, supplements, and rebalances the tear film to help break the cascade of dry eye symptoms and promote a healthy ocular surface environment that helps protect the cornea from damage.

And, what else can you do for your dry, tired eyes?

- Make short pauses from time to time if you work in front of a PC
- Remember to blink regularly
- Provide your room or office with natural air, or consider a humidifier
- Drink enough water
- Protect your eyes from the wind when you go outside
- Consider adjusting your diet to include more Omega 3 and Vitamin B complex

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