


Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name	Artelac Rebalance 10 ml MDO		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	United Kingdom (UK); Ireland (IE)		Nr wykrojnika Spec No	12027	
Opracowane przez Designed by	5536		Kod Wytwórcy Manufacturer code	43024PB781/3-UK	
Nr korekty Proof No	2	Data Date	25.03.2021	Kod farmaceutyczny Pharmacode	305
Kod wersji Valeant version code	P1UKIE05		Inny kod Other code	-	
Rozmiar czcionki Font size	minimum 9 pt		Wymiar ulotki PIL size	120 x 270 mm	
Krój czcionki Font used	FranklinGothicITC Book FranklinGothicITC Demi		Gramatura papieru Paper weight	- g/m ²	
Komentarze Comments (Reason for the change)					
- PMR_ICN-21-0243-A - Legal Manufacturer Address Correction Removal of distributor details for consistency with other pharma MDs Correction of markings and language Packing site: Dr. Gerhard Mann					
Akceptacja Techniczna Technical Approval					
					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 1px solid green; padding: 5px; display: inline-block;"> <p>APPROVED By Claire Dunne at 8:02 am, Apr 09, 2021</p> </div>					

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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, your eye care professional or contact us.

BAUSCH + LOMB

Artelac Rebalance®

0.15% sodium hyaluronate, 0.5% polyethylene glycol 8000 (PEG 8000) and essential electrolytes

Intended use: Eye lubricant and contact lens wetting

What is Artelac Rebalance®?

Artelac Rebalance® is a clear, rosy coloured eye drop solution that contains 0.15% sodium hyaluronate, 0.5% polyethylene glycol 8000 (PEG 8000), potassium chloride, calcium chloride, magnesium chloride, sodium chloride, vitamin B12, water for injection, boric acid and Oxyd® (a gentle preservative that converts to water, oxygen and salt on the surface of the eye).

Once opened it can be used for 2 months.

What is the application of Artelac Rebalance®?

Artelac Rebalance® is an eye lubricant best suited to relieve and calm persistent dry eye symptoms.

Artelac Rebalance® is compatible with all types of both soft and rigid contact lenses during wear and improves the comfort of your contact lenses noticeably, all day long.

When you should use Artelac Rebalance®?

Artelac Rebalance® is designed to remain on the surface of the eye providing long lasting hydration for all dry eye symptoms by supplementing the natural tear film with essential components. It is an ideal product for everybody suffering from a range of symptoms of dry eyes such as tired, stressed, burning and/or tearing eyes.

Dry eyes are caused by

- external factors, like extensive computer use, air conditioning, heating, cigarette smoke, windy outdoor environments as well as 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.

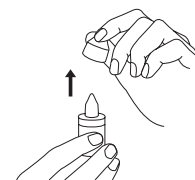
How often and how long should you use Artelac Rebalance®?

Apply 1 drop of Artelac Rebalance® into the eye 3 to 5 times daily, or more frequently if required. Artelac Rebalance® can be used every day as often as necessary.

How to use Artelac Rebalance®?

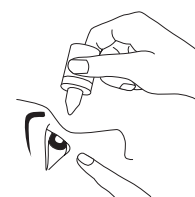
Wash your hands before using the product.

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.

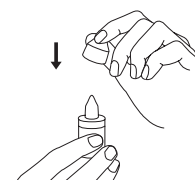


2. Lean your head back slightly and pull your lower eyelid down slightly with a finger of your free hand and hold the bottle vertically above your eye with the nozzle pointing downwards. Then gently squeeze the bottle to apply one drop.

Avoid the top of the bottle coming into contact 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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When you should not use Artelac Rebalance®?

Do not use this product if you are hypersensitive to any of the ingredients.

Important information about using Artelac Rebalance®?

- Local hypersensitivity reactions have been very rarely reported. Treatment should be discontinued in such cases.
- Do not touch the surface of the eye with the tip of the bottle to prevent any possible injury to the surface of the eye or contamination of the solution.
- Wait approximately 15 minutes before using another eye product.
- Do not use after the expiry date.
- Do not use if the package or bottle is damaged.
- Discard the Artelac Rebalance® after 2 months once opened.

How to store Artelac Rebalance®?

Store at a temperature of +2 °C to +25 °C and protect from light!

Symbols

Symbol	Title
Dr. Gerhard Mann chem.-pharm. Fabrik GmbH Brunsbütteler Damm 165/173 13581 Berlin, Germany	Discard the medical device after 2 months once opened
STERILE A	Sterilised using aseptic processing techniques
2°C - 25°C	Temperature limit
	Do not use if packaging is damaged
	Keep away from sunlight

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