

Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		<b>ULOTKA PIL</b>		<b>BAUSCH+LOMB</b>	
Nazwa produktu Product Name		ARTELAC® NIGHT /0.24% sodium hyaluronate, carbomer/		Kolor nadruku Colours	
		Black			
Kraj Country (ISO)		UK, IE		Nr wykrojnika Spec No	
				14842	
Opracowane przez Designed by		Zofia Tabisz-Mikosz Zofia.Tabisz-Mikosz@ bauschhealth.com phone: +48 17 865 5536		Kod Wytwórcy Manufacturer code	
				46007PB999/2-UK	
Nr korekty Proof No		1		Data Date	
				11.03.2021	
Kod wersji Valeant version code		P1UKIE02		Kod farmaceutyczny Pharmacode	
				186	
Inny kod Other code					
Rozmiar czcionki Font size		minimum 9 pt		Wymiar ulotki PIL size	
				148 x 420 mm	
Krój czcionki Font used		Gotham font family		Gramatura papieru Paper weight	
				- g/m <sup>2</sup>	
Komentarze Comments (Reason for the change)					
Legal Manufacturer Address Correction PMR_ICN-21-0237-A Factory (Packing site): DMP Berlin					
Akceptacja Techniczna Technical Approval					
<div style="border: 2px dashed green; padding: 5px; display: inline-block;"> <p><b>GENEHMIGT</b> Von Christina König , 17:13, 18.03.2021</p> </div>					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 2px dashed green; padding: 5px; display: inline-block;"> <p><b>APPROVED</b> By Claire Dunne at 9:14 am, Mar 19, 2021</p> </div>					

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, doctor, eye care professional or contact us.

**BAUSCH+LOMB**

**ARTELAC®  
NIGHT**

0.24% sodium hyaluronate, carbomer, glycerol, lipid component (medium chain triglycerides), sodium hydroxide and water for injection.

**Intended use:** Eye lubricant

#### What is ARTELAC® NIGHT?

Artelac® Night is an opaque eye drop solution that contains 0.24% hyaluronic acid (as sodium hyaluronate), carbomer, glycerol a lipid component (medium chain triglycerides), sodium hydroxide and water for injection.

The advanced formulation possesses a very high tolerability as it is free of preservatives and free of buffers.

The eye drops are presented in a preservative free multi-dose system (PFMD). Once opened, it can be used for 6 months.

#### What is the application of ARTELAC® NIGHT?

Artelac® Night is an eye lubricant that supports all three layers of the tear film to improve the moistening of the ocular surface in the presence of dry eye sensation.

#### When you should use ARTELAC® NIGHT?

Artelac® Night is inspired by the design of the natural tear film. It contains the natural moisturiser hyaluronic acid (as sodium hyaluronate), which is found in the structures of a healthy human eye and the natural tear film and two additional moisturisers: Glycerol and Carbomer. Containing an additional lipid-component (medium chain triglycerides) Artelac® Night supports all three layers of the tear film: lipid, aqueous and mucin layer.

Artelac® Night is designed to remain on the surface of the eye providing intensive moisturisation for immediate, long-lasting symptom relief. It is an ideal product for everybody suffering from a range of symptoms of dry eyes such as tired, stressed, gritty, burning and/or tearing eyes. Use before bed for long-lasting relief from symptoms of dry eyes.

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.

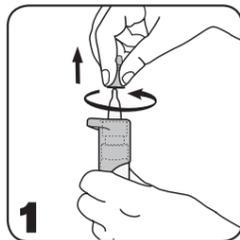
#### How often and how long should you use ARTELAC® NIGHT for?

Apply one drop of Artelac® Night into the eye before bed and as the need arises. You can use it every day and as often as you want. There is no limit to the duration of use.

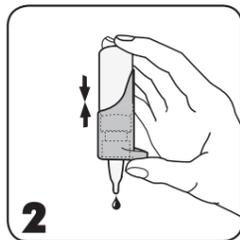
#### How to use ARTELAC® NIGHT?

The patented pump mechanism of Artelac® Night allows the drop solution to be preservative free.

**General note:** Wash your hands before each use. Avoid the tip of the bottle coming into contact with your fingers or your eyes to prevent any possible contamination of the solution or injuries.

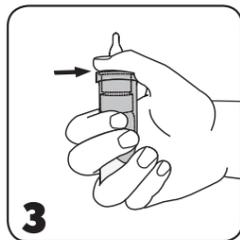


1. Before each use, remove the translucent white protective cap from the tip of the bottle with a rotating movement.



2. **Attention! Before first use and if the bottle has not been used for a while:**

Point the bottle with the tip downwards and press the pump mechanism repeatedly until a drop is released.



3. Hold the bottle as indicated. Place your thumb on the ergonomic thumb support and enclose the lower part with your fingers. Two fingers should be placed on the bottom of the bottle.



4. Point the bottle with the tip downwards. Lean your head back slightly. Gently pull your lower eye-lid down with a finger on your free hand and hold the bottle in a vertical position over your eye. Press the pump mechanism gently together to apply one drop into the eye.

Close your eye afterwards and blink in order to optimally spread the drop on the surface of your eye.

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5. Immediately after use, shake-off any residual drops and replace the translucent white protective cap on the tip of the bottle.

Due to the bottle design, a small amount of solution remains in the bottle. However, the specified filling volume can be completely removed from the bottle.

#### When should you not use ARTELAC® NIGHT?

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

#### Important information about using ARTELAC® NIGHT:

- Local hypersensitivity reactions have been very rarely reported. Treatment should be discontinued in such cases. If you experience persistent discomfort or irritation, stop using the product and consult your doctor.
- Please note that upon the first use or if the product has not been used for a while an initial pumping of the solution is necessary. When pumping the solution, the bottle should be kept with the dropper tip down until a drop is released.
- This product may cause temporary blurred vision after instillation which can have a negative impact on driving vehicles or operating machines.
- 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.
- Shake-off any residual drops after application.
- Once opened, do not share the bottle with anyone else.
- Careless use of the product contrary to the instructions for use could result in the product slipping from your hand which may cause an eye injury.
- Remove contact lenses before use.
- Wait approximately 15 minutes before using another eye product or before replacing contact lenses.
- Discard the medical device after 6 months once opened.
- Do not use after the use-by date.
- Do not use if the packaging or bottle is damaged.
- Artelac® Night is filled in a bottle with small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Artelac® Night should be kept out of reach of children.

#### How to store ARTELAC® NIGHT

Store at a temperature between +1 to +25°C.

The design of the bottle allows you to use Artelac® Night for 6 months after opening.

#### Presentation:

**Artelac® Night** is available as 10 ml eye drops.

#### Symbols

Symbol	Title
	Sterilised using aseptic processing techniques
	Temperature limit
	Do not use if packaging is damaged
	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
	Use-by date
	Batch code
	Manufacturer

#### Manufactured for Bausch + Lomb by:

Dr. Gerhard Mann  
chem.-pharm. Fabrik GmbH  
Brunsbütteler Damm  
165/173, 13581, Berlin, Germany

www.artelac.co.uk



#### ARTELAC® NIGHT/I999EU-03/2021-02

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