


Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name		Artelac Nighttime Gel		Kolor nadruku Colours	
				BLACK	
Kraj Country (ISO)		UK, IE		Nr wykrojnika Spec No	
				12027	
Opracowane przez Designed by		Urszula Zawadzka		Kod Wytwórcy Manufacturer code	
				49822PB174/4-UK	
Nr korekty Proof No		2		Data Date	
				22-03-2021	
Kod wersji Version code		P1UKIE03		Kod farmaceutyczny Pharmacode	
				304	
Rozmiar czcionki Font size		minimum 9 pt		Wymiar ulotki PIL size	
				120 x 270 mm	
Krój czcionki Font used		Franklin Gothic Font Family		Gramatura papieru Paper weight	
				up to manufacturer	
Komentarze Comments (Reason for the change)					
- PMR_ICN-21-0222 - manufacturer & packing site: DMP Berlin - Legal Manufacturer Address Correction - Removal of distributor details for consistency with other pharma MDs - Correction of markings and language - Symbols table headers added and text updated to be consistent with master text					
Akceptacja Techniczna Technical Approval					
					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 1px solid black; padding: 5px; background-color: #e0f0e0;"> <p>APPROVED By Claire Dunne at 2:41 pm, Mar 23, 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 or contact us.

BAUSCH + LOMB

Artelac® Nighttime Gel

2 mg/g carbomer, medium chain triglycerides

Intended use:

Artelac® Nighttime Gel is an eye lubricant.

What is Artelac® Nighttime Gel?

Artelac® Nighttime Gel is an eye gel. 1 g contains 2 mg carbomer, medium chain triglycerides, in addition to sterile water, sorbitol and sodium hydroxide. Cetrimide is used as preservative.

What is the application of Artelac® Nighttime Gel?

Artelac® Nighttime Gel is a highly viscous eye lubricant that supports all three layers of the tear film to provide long-lasting moistening and protection of the ocular surface in the presence of dry eye sensation.

When you should use Artelac® Nighttime Gel:

Artelac® Nighttime Gel is designed to supplement the tear film including the important outer-lipid layer for maximum relief and moisture retention on the surface of the eye. It has a calm and soothing effect on the eyes while at the same time it locks in moisture to provide long term 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. People can also benefit from using this product in addition to their original dry eye product for extra protection.

Dry eyes are caused by

- external factors, like extensive computer use, air conditioning, heating, cigarette smoke, as well as windy outdoor environments and 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 should you use Artelac® Nighttime Gel?

Apply one gel drop of Artelac® Nighttime Gel into the eye 15 min before going to bed if you prefer to use it at night or apply as often as needed during the day.

Important information about using Artelac® Nighttime Gel?

- Local hypersensitivity reactions have been very rarely reported. Treatment should be discontinued in such cases.
- This product may cause temporary blurred vision after instillation which can have negative impact on driving vehicles or operating machines.
- Do not touch the eye surface with the tip of the tube to prevent any possible injury.
- Remove contact lenses before use.
- Wait approximately 15 minutes before using another eye product or before replacing contact lenses.
- Avoid contact of the tip of the tube with your eye or your fingers to prevent any possible contamination of the solution.
- Do not use after the use-by date.
- Do not use if the tube is damaged.

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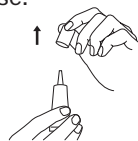


When should you not use Artelac® Nighttime Gel?

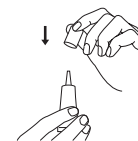
Do not use this product if you are hypersensitive to any of the ingredients.

How you should use Artelac® Nighttime Gel:

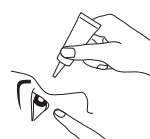
1. Remove the protective cap from the tip of the tube before each use.



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



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



Close your eyelids and slowly move your eye up and down, then blink in order to optimally spread the drop on the surface of your eye.

How to store Artelac® Nighttime Gel?

Store at a maximum temperature of 25°C. Once opened it can be used for 6 weeks.

Symbols			
Symbol	Title	Symbol	Title
	Sterilised using aseptic processing techniques		Use-by date
	Upper temperature limit'		Consult instructions for use
	Do not use if the tube is damaged		Batch code
	Discard any unused eye gel after six weeks of first opening the container		Manufacturer

CE 0483

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