


Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name	ARTELAC® EVERY DAY /sodium hyaluronate/ 0.24%		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	46001PB931/2-UK	
Nr korekty Proof No	2	Data Date	30.03.2021	Kod farmaceutyczny Pharmacode	187
Kod wersji Valeant version code	P1UKIE02		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/m²	
Komentarze Comments (Reason for the change)					
Legal Manufacturer Address Correction PMR_ICN-21-0248-A Factory (Packing site): DMP Berlin					
Akceptacja Techniczna Technical Approval					
					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 2px solid green; padding: 5px; display: inline-block;"> <p>APPROVED By Claire Dunne at 8:24 am, Apr 13, 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, your doctor, your eye care professional or contact us.

BAUSCH + LOMB

ARTELAC®
EVERY DAY

0.24% sodium hyaluronate, sodium chloride, potassium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate-dihydrate and water for injection.

Intended use: Eye lubricant, wetting and rewetting of both soft and rigid contact lenses during wear.

What is ARTELAC® EVERY DAY?

Artelac® Every Day is a clear eye drop solution that contains 0.24% hyaluronic acid (as sodium hyaluronate).

The formulation possesses a very high tolerability as it is free of preservatives. The formulation provides fast and lasting relief of dry eye symptoms.

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® EVERY DAY?

Artelac® Every Day is our first choice product for instantly soothing and hydrating dry eyes. It naturally refreshes and calms your dry eyes relieving symptoms of tired, stressed, even teary eyes.

Artelac® Every Day is suitable for the wetting and rewetting of both soft and rigid contact lenses during wear and improves the comfort of your contact lenses noticeably, all day long.

When should you use ARTELAC® EVERY DAY?

Artelac® Every Day 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.

Artelac® Every Day is designed to remain on the surface of the eye providing instant moisturisation for all dry eye symptoms. It is an ideal product for everybody suffering from a range of mild and moderate 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.

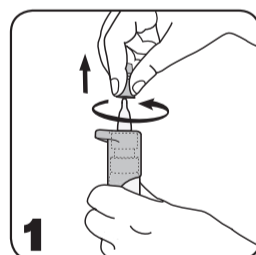
How often and how long should you use ARTELAC® EVERY DAY for?

Apply one drop of Artelac® Every Day into the eye 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.

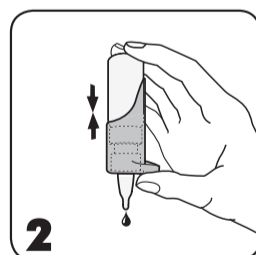
How to use ARTELAC® EVERY DAY

The patented pump mechanism of Artelac® Every Day 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.

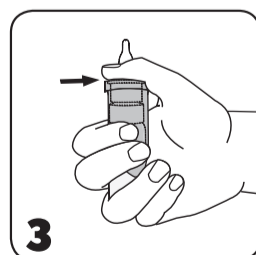


1. Before each use, remove the translucent white protective cap from the tip of the bottle with a rotating movement.



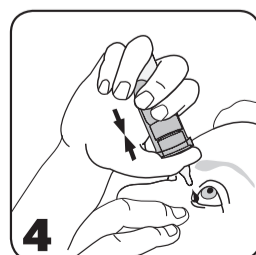
2. **Attention! Before first use and if the bottle has not been used for a while:**

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® EVERY DAY?

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

Important information about using ARTELAC® EVERY DAY:

- 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.
- Safety information for patients with severe damage of the cornea: In very rare cases deposits of calcium phosphate on the cornea were reported during treatment with phosphate-containing products for ophthalmic use.
- 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.
- 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.
- Shake-off any residual drops after application.
- Wait approximately 15 minutes before using another eye product.
- 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® Every Day is filled in a bottle with small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Artelac® Every Day should be kept out of reach of children.

How to store ARTELAC® EVERY DAY

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

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

Presentation:

Artelac® Every Day 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



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