

Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		BAUSCH+LOMB	
Nazwa produktu Product Name	ARTELAC® PROTECT 0.24% sodium hyaluronate, 2% Ectoin		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	46004PB228/2-UK	
Nr korekty Proof No	1	Data Date	10.03.2021	Kod farmaceutyczny Pharmacode	185
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/m ²	
Komentarze Comments (Reason for the change)					
Legal Manufacturer Address Correction Typo correction on carton PMR_ICN-21-0224-A Factory (Packing site): DMP Berlin					
Akceptacja Techniczna Technical Approval					
<div style="border: 1px solid green; border-radius: 10px; padding: 10px; background-color: #e0f0e0;"> <p>GENEHMIGT Von kiriks , 12:12, 15.03.2021</p> </div>					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 1px solid green; border-radius: 10px; padding: 10px; background-color: #e0f0e0;"> <p>APPROVED By Claire Dunne at 8:14 am, Mar 17, 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®
PROTECT

0.24% sodium hyaluronate, 2% Ectoin®, sodium chloride, sodium hydroxide (for pH adjustment) and water for injection.

Intended use: Relieves irritated eyes and protects them from allergens. Provides eye lubrication.

What is ARTELAC® PROTECT?

Artelac® Protect contains Ectoin®, a natural cell-protective molecule with inflammation reducing and membrane stabilising properties and hyaluronic acid a natural molecule which comforts the eye by its high water binding and stabilising characteristics.

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

What is the application of ARTELAC® PROTECT?

Artelac® Protect is an isotonic eyedrop solution which can be used to treat and prevent symptoms of seasonal and perennial allergic conjunctivitis caused by e.g. pollen, dust mites, animal hair, or mold. Itchy, irritated, red or watery eyes will be reduced effectively and their lubrication will result in relief.

Based on the available data the product can be used by adults, children, pregnant and breast-feeding women.

When should you use ARTELAC® PROTECT?

Artelac® Protect stabilises the natural tear film in two ways: hyaluronic acid (as sodium hyaluronate) has a positive impact on the aqueous phase and Ectoin® strengthens the lipid phase. This dual mode of action protects the eye against harmful influences of allergens and other external factors and supports the regeneration process of irritated and sensitive conjunctiva. Artelac® Protect is free of preservatives and suitable for wearers of contact lenses and sensitive eyes.

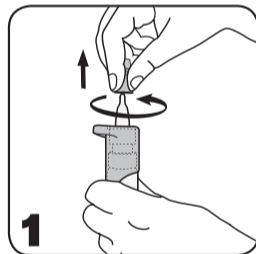
How often and how long should you use ARTELAC® PROTECT for?

Apply 1-2 drops of Artelac® Protect 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.

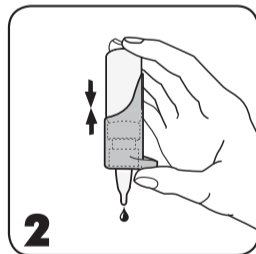
How to use ARTELAC® PROTECT?

The patented pump mechanism of Artelac® Protect 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.

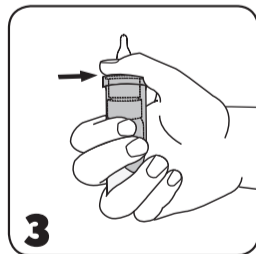


1. Before each use, remove the translucent white protective cap from the tip of the bottle with a rotating movement.

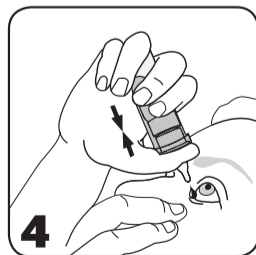


2. Attention! Before first use and if the bottle has not been used for a while:

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.

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® PROTECT?

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

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Important information about using ARTELAC® PROTECT:

- 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.
- Artelac® Protect is suitable for use with soft and rigid contact lenses.
- 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® Protect is filled in a bottle with small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Artelac® Protect should be kept out of reach of children.

How to store ARTELAC® PROTECT

Store at a temperature between +2 to +25°C.

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

Presentation:

Artelac® Protect 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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