

Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		<b>BAUSCH + LOMB</b>	
Nazwa produktu Product Name	ARTELAC HYDRA SPRAY 10 ml		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	UK; IE		Nr wykrojnika Spec No	14842	
Opracowane przez Designed by	Łukasz Kozioł lukasz.kozioł@valeant.com Phone: +48 17 865 5537		Kod Wytwórcy Manufacturer code	43334PB898/1-UK	
Nr korekty Proof No	3	Data Date	10-12-2020	Kod farmaceutyczny Pharmacode	115
Kod wersji Valeant version code	P1UKIE01		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 Helvetica font family		Gramatura papieru Paper weight	- g/m <sup>2</sup>	
Komentarze Comments (Reason for the change)					
NEW LAUNCH PMR_ICN-20-1243-A Factory (Packing site): DMP BERLIN					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

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, eye care professional or contact us

**BAUSCH + LOMB**

# ARTELAC®

## HYDRA PLUS Performance Eye Spray

**Composition:** 0.05% sodium hyaluronate, carbomer, glycerol, lipid component, sodium hydroxide and water for injection.

**Intended use:** Lubrication of eyes and eyelids.

### What is ARTELAC® HYDRA PLUS Performance Eye Spray?

ARTELAC® HYDRA PLUS Performance Eye Spray is a sterile ophthalmic solution that contains 0.05% 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 ophthalmic spray is presented in a preservative free multi-dose system (PFMD), which is easy to use. Once opened, it can be used for 6 months.

### What is the application of ARTELAC® HYDRA PLUS Performance Eye Spray?

ARTELAC® HYDRA PLUS Performance Eye Spray 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 applied on closed eyes, it provides a refreshing sensation.

### When should you use ARTELAC® HYDRA PLUS Performance Eye Spray?

ARTELAC® HYDRA PLUS Performance Eye Spray 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® HYDRA PLUS Performance Eye Spray supports all three layers of the tear film: lipid, aqueous and mucin layer.

ARTELAC® HYDRA PLUS Performance Eye Spray is suitable to be used on open and closed eyes (eyelids). It is a lubricating solution in a spray format that provides intensive moisturisation and gives a refreshing feeling when used on open eyes. It is designed for immediate, long-lasting symptomatic relief of dry eyes such as tired, stressed, gritty, burning and/or tearing 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.

When used on closed eyes, ARTELAC® HYDRA PLUS Performance Eye Spray provides a refreshing feeling to eyelids and the periocular surface and provides quick relief for cases of skin desquamation, eyelid irritations and eye allergies. It can be used as a coadjuvant in the treatment of blepharitis and blepharoconjunctivitis.

- Dual action with quick and easy application – spray on closed eyelids to refresh and rejuvenate tired eyes or apply directly to the eye surface whilst blinking to quickly rehydrate and stabilise the natural tear film.
- Moisturises the eyelids and the periocular area.
- Long-lasting moisturisation for immediate relief.
- For long-term users.
- Quickly rehydrates/lubricates and stabilises the natural lipid layer of the eyes and tear film.
- It contains Hyaluronic Acid to replenish the eye's protective moisture layer. It contains a lipid component which works to replenish the lipid layer of your tear film, naturally lubricating the eyes by locking in moisture.
- The spray format quickly rehydrates & protects the eyes, eyelids and periocular area.

### How often and how long should you use ARTELAC® HYDRA PLUS Performance Eye Spray for?

Apply 1-2 sprays of ARTELAC® HYDRA PLUS Performance Eye Spray into the eye or on to the eyelids 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. ARTELAC® HYDRA PLUS Performance Eye Spray is very tolerable as it is free of any preservatives and buffers.

### How to use ARTELAC® HYDRA PLUS Performance Eye Spray?

The patented pump mechanism of ARTELAC® HYDRA PLUS Performance Eye Spray allows the ophthalmic solution to be preservative free. **General note:** The ophthalmic spray is designed to be used on open and closed eyes (eyelids).

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1. Before each use, remove the translucent white protective cap from the sprayer of the bottle by pulling upwards.



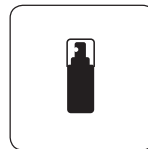
2. **Attention! Before first use and if the bottle has not been used for a while:** Press the pump mechanism repeatedly up to 5 - 10 times until a consistent spray pattern is released.



3. Application on open eyes: Bring the nebuliser to about 10cm from the eye whilst blinking, in a lateral position to the side of your face and press the pump mechanism quickly until the spray is released.



4. Application on closed eyes or eyelids: Hold the bottle at about 10cm from your closed eyelid and press the pump mechanism quickly until the spray is released, then blink.



5. Immediately after use, replace the translucent white protective cap on the sprayer of the bottle.

#### When should you not use ARTELAC® HYDRA PLUS Performance Eye Spray?

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

#### Important information about using ARTELAC® HYDRA PLUS Performance Eye Spray

- 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 usage or after non-usage for a while, an initial pumping of the system is necessary.
- Do not touch the tip of the bottle with fingers or other surfaces to prevent contamination of the solution.
- 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® HYDRA PLUS Performance Eye Spray contains small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, ARTELAC® HYDRA PLUS Performance Eye Spray should be kept out of the reach of children.

#### How to store ARTELAC® HYDRA PLUS Performance Eye Spray?

Store at a temperature between +2 and +25°C

The design of the bottle allows you to use ARTELAC® HYDRA PLUS Performance Eye Spray for 6 months after opening.

#### Presentation:

ARTELAC® HYDRA PLUS Performance Eye Spray is available as a 10ml eye spray.

#### Explanation of Symbols

Symbol	Title
	Sterilised using aseptic processing techniques
	Temperature limit
	Do not use if packaging or bottle 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
	Conformity Assessment to European Medical Device Directive CE mark with notified body number

#### 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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