

R&D Bausch + Lomb		ULOTKA PIL. BAUSCH + LOMB	
Nazwa produktu Product Name	Biotrue Night Time Relief MultiDose 10mL		Kolor nadruku Colours
	Black		
Kraj Country (ISO)	Canada (CA)		Nr wykrojnika Spec No
Opracowane przez Designed by	Tracy Grier tracy.grier@lausch.com +1-605-338-5299	Kod Wytwórcy Manufacturer code	43529PB999/1-CA
Nr korekty Proof No	2	Data Date	05-10-2023
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Komentarze Comments (Reason for the change)			
PMR_BNL-23-0347-A Geoexpansion - Biotrue Night Time Relief Eye Drops 10ml <999> Launch for CANADA Factory (Packing site): DMP Berlin			
Akceptacja Techniczna Technical Approval			
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Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval			
<div style="border: 1px dashed #ccc; padding: 5px; margin-bottom: 5px;"> DocuSigned by:  Cecile Cuating </div> <div style="border: 1px dashed #ccc; padding: 5px;"> 10/19/2023 </div>			

DocuSigned by:

Brando Santini

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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 eye care professional or contact us.

BAUSCH + LOMB

**Bio
true**
eye gel drops

Inspired by the nature of your eyes**What is Biotrue® Night Time Relief?**

Biotrue® Night Time Relief is a preservative free opaque eye drop solution that contains 0.24% of the clinically proven natural moisturizer hyaluronic acid (as sodium hyaluronate), found in the structures of a healthy human eye and the natural tear film. This product is intended to use as an eye lubricant, before bed, that supports all the layers of the tear film to improve the moistening of the ocular surface in the presence of dry eye sensation. Biotrue® Night Time Relief possesses a very high tolerability as it is preservative free and buffer free. Biotrue® Night Time Relief is presented in an innovative preservative free multi-dose system (PFMD), which is easy and safe to use. Once the bottle is opened, it can be used for up to 6 months.

When should you use Biotrue® Night Time Relief?

Biotrue® Night Time Relief is inspired by the design of the natural tear film. It contains the natural moisturizer hyaluronic acid (as sodium hyaluronate), and two additional moisturizers: Glycerol and Carbomer. Containing an additional lipid-component (medium chain triglycerides) Biotrue® Night Time Relief is supporting all three layers of the tear film: lipid, aqueous and mucin layer.

Biotrue® Night Time Relief is designed to remain on the surface of the eye providing intensive moisturization for immediate, long-lasting symptom relief. It is a suitable product for those suffering from a range of symptoms of dry eyes, such as tired, stressed, gritty, burning and/or tearing eyes.

Dry eyes can be caused by a number of factors, both physical and environmental:

- external factors, like extensive computer use, air conditioning, heating, cigarettes smoke, as well as windy outdoor environments and/or wearing contact lenses.
- Lasik surgery;
- taking certain drugs such as the contraceptive pill, antihistamines, betablockers, antispasmodics and diuretics
- certain diseases that play a role in the development of ocular dryness such as diabetes, rheumatoid arthritis, or thyroid problems.

How often and for how long should you use Biotrue® Night Time Relief?

Instill 1 drop of Biotrue® Night Time Relief into the eye before bed and as needed. Its preservative free formulation makes the product suitable to use every day and as often as needed. There is no limit to the duration of use.

What ingredients does Biotrue® Night Time Relief contain?

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

How to use Biotrue® Night Time Relief?

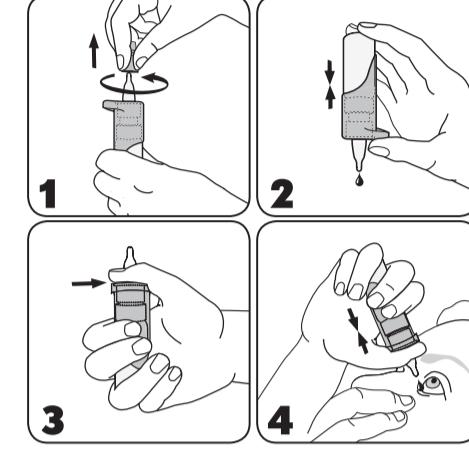
The patented pump mechanism of the Biotrue® Night Time Relief bottle allows the eye drop solution to be preservative free, safe, and easy to use.

1. Before each use, wash your hands and remove the protective cap from the tip of the bottle with a rotating movement. Avoid contact of the tip of the bottle with your fingers or any other surfaces to prevent any possible contamination of the solution.

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 repeatedly the pump mechanism until a drop is released. Now the bottle is ready to use.

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

4. Lean your head back slightly and gently pull your lower eyelid down with a finger of your free hand. Hold the bottle in a vertical position over your eye and press the pump mechanism together to apply one drop into the eye. Close your eye afterwards, slowly move it back and forth and then blink your eyes in order to optimally spread the drop on the surface of your eye. Avoid touching the surface of your eye with the bottle tip to prevent any possible injury and/or contamination of the solution. Replace the protective cap on the tip of the bottle immediately after use.

**When should you not use Biotrue® Night Time Relief?**

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

Important information about using Biotrue® Night Time Relief:

- Please note that prior to the first usage or after a period of non-use, an initial pumping of the bottle is necessary. While doing so, keep the dropper tip down and away from the eyes, as shown in Figure 2.
- 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.
- 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 bottle to prevent any possible injury of the eye surface and/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 slipping a product from hand and may cause eye injury.
- Shake off any possible residual drops after application.
- Remove contact lenses before usage.
- Wait approximately 15 minutes before using another eye product or before replacing contact lenses.
- Biotrue® Night Time Relief can be used for up to 6 months after the bottle is opened. The bottle should be discarded after that time. To help you remember, the label on the bottle has a space where you can note when the bottle was first opened.
- Do not use beyond expiry date.
- Do not use if product packaging and/or bottle are damaged.
- Biotrue® Night Time Relief contains small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Biotrue® Night Time Relief should be kept out of reach of children.
- The product can be used for pregnant, breastfeeding women and children. If your child is experiencing dry eyes, consult a doctor before using an eye lubricant.

How to store Biotrue® Night Time Relief?

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

 +1°C → +25°C Store between +1°C and +25°C.

 Discard the bottle 6 months after and/or bottle are damaged

 LOT Batch code

 STERILE A Sterilization method, aseptic

 Caution: Consult the "Instructions for use" for important cautionary information, such as warnings and precautions

Questions? 1-888-459-5000

www.BiotrueEyeDrops.ca

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MANUFACTURER COUPON

Save \$3.00

on any one (1) Biotrue® Eye Drops or Biotrue® Night Time Relief

CONSUMER: Valid at participating retailers and pharmacies only. Coupon must be presented to cashier at time of purchase. Offer cannot be combined with any other offer.

DEALER/RETAILER: Bausch + Lomb Canada will reimburse the face value of the coupon plus regular handling fee provided you accept it from your customer on purchase of item specified. Other applications may constitute fraud. Failure to send in, on request, evidence that sufficient stock was purchased in previous 90 days to cover coupons presented will void coupons. Coupons submitted become our property. Reimbursement will be made only to retail distributor who redeemed coupon. A reduction in any applicable taxes payable is included in the coupon face value. For redemption, mail to: Bausch + Lomb Canada, PO Box 3100, Scarborough, ON, M1R 0E7.

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