

R&D  
Bausch + Lomb

ULOTKA PIL

BAUSCH + LOMB

Nazwa produktu  
Product Name

Soothe  
Preservative Free  
Dry Eye Therapy  
EYE DROPS  
/Sodium Hyaluronate  
2.4 mg/mL

Kolor nadruku Colours

Black

Kraj  
Country (ISO)

Canada (CA)

Nr wykrojnika  
Spec No

14842

Opracowane przez  
Designed by

Tracy Grier  
tracy.grier@bausch.com

Kod Wytwórcy  
Manufacturer code

43078PB931/4-CA

Nr korekty  
Proof No

3

Data  
Date

13.12.2023

Kod farmaceutyczny  
Pharmacode

371

Kod wersji  
Valeant version code

P1CA04

Inny kod  
Other code

-

Rozmiar czcionki  
Font size

EN text minimum 8 pt  
FR text minimum 7,5 pt  
(Manufacturer Coupon  
minimum 6 pt)

Wymiar ulotki  
PIL size

148 x 420 mm

Krój czcionki  
Font used

Helvetica Neue LT W1G  
font family

Gramatura papieru  
Paper weight

- g/m²

Komentarze Comments (Reason for the change)

Reference: LCRF-2023-009 - Soothe PF Dry Eye Therapy 10ml  
1. Corrected French name: „Traitment“ to „Traitement“  
2. Updated distributor info to remove references to Bausch Health  
3. Updated coupon code and expiry date on LEAFLET only

PMR\_BNL-23-0391-A

Factory (Packing site): DMP Berlin

Akceptacja Techniczna Technical Approval

GENEHMIGT

Von Franka Bessem , 12:13, 14.12.2023

Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval

APPROVED

By Cecile Cualing at 12:16 pm, Mar 08, 2024

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APPROVED

By Gaganpreet Bassi at 10:10 am, Mar 08, 2024

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.

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Soothe®  
Preservative Free  
Dry Eye Therapy

**What is Soothe® Preservative Free Dry Eye Therapy?**  
Soothe® Preservative Free Dry Eye Therapy is a preservative free clear 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. It provides instant soothing and natural hydration for dry eyes and offers fast, long lasting relief of tired, stressed, burning and teary eyes. Soothe® Preservative Free Dry Eye Therapy is free of preservatives and is gentle enough for sensitive eyes and post-operative dryness. It is suitable for the wetting and rewetting of both soft and rigid contact lenses during wearing, and noticeably improves the comfort of the contact lenses. Soothe® Preservative Free Dry Eye Therapy is presented in the 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 Soothe® Preservative Free Dry Eye Therapy?**  
Soothe® Preservative Free Dry Eye Therapy is designed to remain on the surface of the eye, instantly moisturizing it to relieve dry eye symptoms. It is an ideal product for people suffering from a range of symptoms of dry eyes, such as tired, stressed, burning or teary eyes. Dry eyes can be caused by a number of factors, both physical and environmental:

- external factors, such as prolonged use of digital devices, air conditioning, heating, cigarettes smoke, windy outdoor environments as well as wearing contact lenses;
- post-operative (i.e. LASIK, cataract surgery);
- taking certain drugs, such as birth control pills, antihistamines, high blood pressure medicines, heart medicines, pain relievers, anti-inflammatories and diuretics;
- tear glands slowing down tear production – a normal occurrence that happens with age, especially in women going through menopause;
- 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 Soothe® Preservative Free Dry Eye Therapy?**  
Instill 1 or 2 drops of Soothe® Preservative Free Dry Eye Therapy in the eye as needed. Its preservative free formulation makes the product suitable to use every day and as often as needed throughout the day. Soothe® Preservative Free Dry Eye Therapy can be used for as long as needed. If you are using this product for post-operative (e.g. LASIK) dryness and discomfort, follow your eye doctor's instructions.

**What ingredients does Soothe® Preservative Free Dry Eye Therapy contain?**  
0.24% sodium hyaluronate, sodium chloride, potassium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate-dihydrate, water for injection.

**How to use Soothe® Preservative Free Dry Eye Therapy?**  
The patented pump mechanism of the Soothe® Preservative Free Dry Eye Therapy 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.

Avoid touching the surface of your eye with the bottle tip to prevent any possible injury and/or contamination of the solution.

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.

Immediately after use, shake off any possible residual drops and place the protective cap back on the dry tip of the bottle.

The Soothe® Preservative Free Dry Eye Therapy bottle releases 10 mL of eye drop solution. Due to the bottle design, a small amount of additional solution remains in the bottle.

**When should you not use Soothe® Preservative Free Dry Eye Therapy?**  
Do not use this product if you are hypersensitive to any of its ingredients.

**Important information about using Soothe® Preservative Free Dry Eye Therapy:**

- Soothe® Preservative Free Dry Eye Therapy should not be used if you are hypersensitive to any of its ingredients.
- 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.
- Safety information for patients with severe damage of the cornea: In very rare cases, deposits of calcium phosphate on the cornea have been reported during treatment with phosphate-containing products for ophthalmic use.
- 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.
- Wait approximately 15 minutes before using another eye product.
- Soothe® Preservative Free Dry Eye Therapy can be used for up to 6 months after the bottle is opened and 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.
- Soothe® Preservative Free Dry Eye Therapy is filled in a bottle with small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Soothe® Preservative Free Dry Eye Therapy should be kept out of reach of children.

**How to store Soothe® Preservative Free Dry Eye Therapy?**  
Store between +1°C and +25°C.

+1°C

+25°C

Store between +1°C and +25°C.

6M

Discard the bottle 6 months after opening it for the first time.

LOT

Batch code

STERILE A

Sterilization method, aseptic

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

Do not use if product packaging and/or bottle are damaged

Expiry date

Consult instructions for use

Questions? 1-888-459-5000  
www.SootheEyeDrops.ca  
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MANUFACTURER COUPON

Save \$3.00 on any one (1) Soothe® Preservative Free Dry Eye Therapy 10ml

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: Upon presentation of this coupon by your customer toward the purchase of the specified product, 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 31000, Scarborough, ON, M1R 0E7.

Expiry date: December 31, 2026

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Soothe®  
Preservative Free  
Dry Eye Therapy

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