

PLEASE READ CAREFULLY AND KEEP THIS PACKAGE INSERT FOR FUTURE USE IN CASE YOU HAVE A PROBLEM.

BAUSCH + LOMB

ScleralFil®

PRESERVATIVE FREE SALINE SOLUTION

CONTENTS: ScleralFil® preservative free saline solution is a sterile buffered isotonic saline solution that has boric acid, sodium borate, and sodium chloride in purified water. ScleralFil preservative free saline solution has NO preservative or mercury-containing ingredients (e.g., chlorhexidine, thimerosal) to which some people are sensitive. Use ScleralFil preservative free saline solution only with soft (hydrophilic), rigid gas permeable, hard, and large diameter (scleral) contact lenses.

ACTIONS: ScleralFil preservative free saline solution removes loosened debris and traces of daily cleaner when used as a rinse after cleaning. ScleralFil preservative free saline also keeps your lens wet (hydrated).

INDICATIONS (USES): ScleralFil preservative free saline solution is a sterile, preservative free solution indicated for use following proper lens disinfection as recommended by the eye care practitioner. ScleralFil preservative free saline solution is indicated for:

- rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion
- as an insertion solution for large diameter (scleral) contact lenses
- as a rinse for contact lens cases
- rinsing contact lenses throughout the day.

CONTRAINDICATIONS (REASONS NOT TO USE): If you are allergic to any ingredient in ScleralFil preservative free saline solution, do not use this product.

PRECAUTIONS:

- Always follow the product directions for use. Failure to follow product directions may lead to vision loss.
- Visit your eye care practitioner regularly.
- Always wash and dry hands before handling lenses.
- Do not use tap water, bottled water or saliva with lenses or lens cases.
- Only use fresh solution to clean and disinfect contact lenses.
- Always discard any remaining solution in your lens case after each disinfection cycle (Never re-use solution).

- Saline or rewetting drops will not disinfect your lenses.
- Always replace your solution, lenses and lens case as directed.
- Discard the bottle and remaining contents right after use.
- Never re-use or "top off" the solution in your lens case.
- Store at room temperature.
- Use before expiration date on bottle and carton.
- Keep out of reach of children.

WARNINGS:

Because ScleralFil preservative free saline solution contains no preservatives; it will not remain sterile indefinitely after opening and, therefore, should not be used as an eye drop. ScleralFil preservative free saline solution is intended for single use. Discard any unused portion of the solution. DO NOT use after expiration date.

ScleralFil preservative free saline solution is a clear solution. DO NOT USE SOLUTION IF IT IS CLOUDY OR DISCOLORED or if the bottle LEAKS before you open it.

DO NOT USE saline or tap water for the storage of contact lenses, which may cause serious and sight-threatening eye infections such as Acanthamoeba, causing corneal ulcers and possibly permanent loss of sight.

DO NOT use ScleralFil preservative free saline solution for storage.

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reaction is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incident of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have shown that smokers have a higher incidence of adverse reactions.

If you experience eye discomfort, excessive tearing, vision changes, redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner.

It is recommended that contact lens wearers see their eye care practitioner twice each year or, if directed, more frequently.

To avoid contamination and possible eye infection, DO NOT touch the open tip of the container to any surface.

To avoid contamination and possible eye infection, DO NOT transfer to other bottles or containers.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submerged in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

ADVERSE REACTIONS (Problems and what to do): The following problems may occur: eye sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above:

• IMMEDIATELY REMOVE YOUR LENSES.

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, DO NOT put the lens back on your eyes. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eye lash, or other foreign body on it, or the problem stops and the lens appear undamaged, thoroughly clean, rinse, and **disinfect** the lenses, then reinsert it.
- If the problem continues, **IMMEDIATELY** remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition, such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage (See your **Instruction for Wearers** booklet for more information.)

GOOD LENS CARE PRACTICES:

- Always wash and dry your hands before handling lenses.
- Clean, rinse and disinfect your lenses each time you remove them.
- Always handle the same lens first, the right or left, in order to avoid mix-ups.
- After use, always empty and rinse lens case with fresh rinsing solution and allow to air dry.

- Clean contact lens cases with digital rubbing with fresh, sterile disinfecting solutions/contact lens cleaner. Never use water.
- Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended.
- Air-drying or recapping the lens case lids after use without any additional cleaning methods should be discouraged. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace the lens case as directed by the recommendations of your eye care practitioner. Contact lens cases can be a source of microbial growth.

DIRECTIONS FOR USE: Twist-off the plastic cap to open the ScleralFil® preservative free saline solution vial. Discard the cap. Follow these directions:

1. Always wash and dry your hands before handling lenses.
2. Always handle the same lens first, the right or left, in order to avoid mix-ups.
3. Following proper lens disinfection:
 - For soft (hydrophilic), hard, hybrid, and rigid gas permeable contact lenses, apply several drops to each lens surface to rinse lens prior to insertion.
 - For large diameter (scleral) contact lenses rinse both sides of the lens and fill the back surface before insertion.
 - For contact lens cases rinse all the inner surfaces of the case and the lids and allow to air dry in a clean place.
 - For rinsing lenses during the day remove the lens, rinse both surfaces with several drops of ScleralFil preservative free saline solution and re-insert the lenses.

4. Discard single use vial after each use. Do not re-use.

HOW SUPPLIED: ScleralFil preservative free saline solution is available for purchase in sterile 0.33 Fl. Oz. (10 mL) single-use twist-off top plastic bottles that are packaged in cartons of 30 units each. Bottles and cartons are marked with a lot number and expiration date.

LENSES: ScleralFil preservative free saline solution is for use with soft (hydrophilic), rigid gas permeable, hard, and large diameter (scleral) contact lenses.

Toll Free Product Information

Call: 1-800-553-5340

Distributed by:

Bausch & Lomb Americas Inc.
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

ScleralFil is a trademark of Bausch & Lomb Incorporated or its affiliates.

© 2023 Bausch & Lomb Incorporated or its affiliates

Made in Taiwan.

3819201



WebCenter Approval Information

Page: 2 of 3
Project: Asset 3819201
Document: 3819201_ScleralFil PF Saline Solution_Insert_US_CMO_APPROVED.pdf
Document description:
Version: 3
Version ID: 00002_0000314443
Downloaded: Dec 13, 2023 at 3:42 PM GMT-05:00
By: Nebard, Rebekah-Mkt_Pur_Ops (NEBARDR)
Approval state:

Approved

Sta ge Nr	Approver	Role / Group	Date and Time	Action	Comment
1	Shirley, Patrick- Graphics QA (SHIRLEP), Bausch Health Company (Rochester_US)	RA GRAPHICS QC	Oct 19, 2023 at 1:56 PM GMT-05:00	Approved (GQC Review Cycle)	
2	Soehner, Christina-RA Proofreader (CHRISTINA. SOEHNER), Bausch Health Company (Bridgewater_US)	RA PROOF READER	Oct 23, 2023 at 9:40 AM GMT-05:00	Approved (Mock Up Review Cycle)	
3	Malone, Jennifer-RA Project Lead (JENNIFER.MALONE), Bausch Health Company (Bridgewater_US)	RA PROJECT LEAD	Oct 23, 2023 at 12:08 PM GMT-05:00	Approved (Mock Up Review Cycle)	
4	Nebard, Rebekah- Mkt_Pur_Ops (NEBARDR), Bausch Health Company (Wilmington_US)	MARKETING	Oct 24, 2023 at 9:51 AM GMT-05:00	Approved (Stage1)	
5	Begley, Sade- Regulatory (BEGLEYS), Bausch Health Company (Rochester_US)	REGULATORY	Oct 24, 2023 at 11:06 AM GMT-05:00	Approved (Stage2)	



WebCenter Approval Information

Page: 3 of 3

Stage Nr	Approver	Role / Group	Date and Time	Action	Comment
5	Soehner, Christina-RA Proofreader (CHRISTINA. SOEHNER), Bausch Health Company (Bridgewater_US)	RA PROOF READER	Oct 24, 2023 at 1:11 PM GMT-05:00	Approved (Stage2)	
6	Malone, Jennifer-RA Project Lead (JENNIFER.MALONE), Bausch Health Company (Bridgewater_US)	RA PROJECT LEAD	Oct 24, 2023 at 1:53 PM GMT-05:00	Approved (Stage3)	
7	Blankenship, Sarah- Graphics Lead (BLANKES), Bausch Health Company (Rochester_US)	RA GRAPHICS LEAD ALL	Oct 27, 2023 at 3:48 PM GMT-05:00	Approved (Stage4)	