

VibrantVue® Scleral Saline

Package Insert

Please read carefully and keep this package insert for future reference.

DESCRIPTION: The VibrantVue® Scleral Saline is a sterile, preservative-free, unbuffered saline solution in a single dose 5 ml vial. The VibrantVue® Scleral Saline is a 0.9% saline solution that conforms to the requirements of USP saline. The rinsing solution removes loose debris and lens cleaners off rigid gas permeable (RGP) contact lenses following proper disinfection as recommended by the eye care practitioner. The sterile solution can be used to rinse contact lens cases and contact lenses as needed throughout the day.

ACTIONS: VibrantVue® Scleral Saline removes loosened debris and traces of daily cleaner when used as a rinse after cleaning and prior to lens insertion. VibrantVue® Scleral Saline also helps keep your lenses hydrated and helps provide a liquid reservoir between the lens and cornea when used as an insertion solution with low fluid exchange contact lenses.

INDICATIONS (USES): VibrantVue® Scleral Saline is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The VibrantVue® Scleral Saline is for rinsing large diameter (scleral) rigid gas permeable (RGP) contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE): If you are allergic to any ingredient in VibrantVue® Scleral Saline, do not use this product.

TAMPER EVIDENT: Single use vials should not be used if opened or damaged.

WARNINGS: DO NOT use VibrantVue® Scleral Saline for the storage of contact lenses. This product should only be used as an insertion solution and rinsing contact lenses and lens cases. Use of VibrantVue® Scleral Saline for storage may cause serious and sight-threatening eye infections such as Acanthamoeba, causing corneal ulcers and possibly permanent loss of sight. Use only if tab and unit dose vial are intact.

This product is provided in a single dose package that does not contain preservatives. To minimize the risk of contamination and possible eye infection, DO NOT save and reuse any unused saline. Discard the package immediately after use.

DIRECTIONS FOR USE:

General Instructions: Use only the solutions recommended by your eye care practitioner. Seek advice from your eye care practitioner before making any changes to your care regimen to ensure compatibility with lenses.

Always follow the directions for use in the labeling included with each solution as instructions may be different for each solution.

Specific Instructions: Twist off the plastic cap to open VibrantVue® Scleral Saline. Discard the cap and 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; rinse both sides of the lens and fill back surface (bowl) before insertion.
4. **Discard single use vial after each use. DO NOT REUSE.**

PRECAUTIONS: Never reuse this solution. Always wash and dry your hands before handling your lenses.

LENS CASE CARE INSTRUCTIONS: Empty and clean contact lens cases with digital rubbing

using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with VibrantVue® Scleral Saline or with fresh, sterile disinfecting solutions (never use tap water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

Replace your lens case according to the directions given to you by your eye care practitioner or the labeling that came with your case.

Contact lens cases can be a source of growth of harmful microorganism.

WARNING: Do not store your lenses or rinse your lens case with water or any non-sterile solution. If you use multi-purpose solution use only fresh solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss of blindness.

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 of your lenses and lens care products including the lens storage 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. IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

It is recommended that contact lens wearers should see their eye care practitioner once each year, or more often, as recommended by their

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

To avoid contaminating your solution, do not transfer to other bottles or containers. Reuse of solution or use of water with lenses may lead to contamination resulting in eye injury and potential loss of vision. See below for additional important safety information.

Important Safety Information:

Always follow the product directions for use. Failure to follow product directions may lead to vision loss.

Visit your eye care practitioner once each year, or more often, as recommended by your eye care practitioner.

Always wash and dry hands before handling lenses.

Do not use tap water, bottled water or saliva with lenses or lens case.

Only use fresh solution to clean and disinfect contact lenses.

Discard any remaining solution in your lens case after each disinfection cycle.

Do not reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. “Topping-Off” is the addition of fresh solution to solution that has been sitting your case.

Saline or wetting drops will not disinfect your lenses.

Always replace your solutions, lenses and lens case as directed.

Not for use with heat (thermal) disinfection.

Store at room temperature.

Use before the expiration date marked on the carton and container.

Keep this and all medication out of reach of children.

WATER ACTIVITY INSTRUCTIONS: Do not expose your contact lenses to water while you are wearing them. **WARNING:** Water can harbor microorganisms that can lead to severe infection, vision loss of blindness. If your lenses have been submerged in water while swimming in pools, lakes or oceans, you should replace them or thoroughly clean and disinfect them (RGP and hard lenses) before insertion. Ask your eye care practitioner for recommendations about wearing your lenses during any activity involving water.

ADVERSE REACTIONS (Problems and What to Do):

The following problems may occur:

Eyes stinging, burning or itching (irritation).

Excessive watering (tearing) of the eyes.

Unusual eye secretions.

Redness of the eyes.

Reduced sharpness of vision (visual acuity).

Blurred vision.

Rainbows or halos around objects.

Sensitivity to light (photophobia).

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 eye. Place the lens in the storage case and contact your eye care practitioner.

- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.
- If the problem continues, IMMEDIATELY remove the lens and consult your eye care practitioner.

If any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Seek immediate professional identification of the problem and treatment to avoid serious eye damage.

All adverse reactions observed while using VibrantVue® Scleral Saline should be reported to:

Dry Eye Innovations LLC

(833) 984-2359 [Toll Free] www.vibrantvue.com

HOW SUPPLIED: VibrantVue® Scleral Saline is available in sterile 5 ml disposable single-use twist-off top plastic vials that are packaged in cartons of 100 units each. Vials and cartons are marked with lot number and expiration date.

Toll Free Product Information:

Call: (833) 984-2359 [Toll Free]

VibrantVue Scleral Saline is a registered trademark of Dry Eye Innovations LLC

Manufactured in USA