

Attention AOSEPT USERS, this package insert reflects the most current information as to the use of this product. Please read carefully and keep this information for reference.



AOSEPT DISINFECTING SOLUTION PACKAGE INSERT

DESCRIPTION: AOSEPT® Disinfecting Solution is a sterile solution containing micro-filtered hydrogen peroxide 3%, sodium chloride 0.85%, stabilized with phosphonic acid, and buffered with phosphates.

The AOSEPT System consists of the following: • AOSEPT Disinfecting Solution • AOSEPT Disposable Cup & Disc

Additional products recommended for use with the AOSEPT System: • Focus® Lens Drops • Miraflow® Extra-Strength Daily Cleaner • Softwear® Saline • Unizyme® Enzymatic Cleaner

ACTION: AOSEPT Disinfecting Solution kills microorganisms on soft (hydrophilic) contact lenses that could cause serious eye infections.

INDICATIONS: AOSEPT Disinfecting Solution is for use in the AOSEPT System to disinfect daily and extended wear, clear and tinted soft (hydrophilic) contact lenses.

NOTE: AOSEPT Disinfecting Solution contains no thimerosal or chlorhexidine preservative to which some people are sensitive.

CONTRAINDICATIONS (Reasons not to use): None are known; however, if you are allergic to any ingredient in AOSEPT Disinfecting Solution, do not use this product.

WARNINGS:

• DO NOT PUT AOSEPT DISINFECTING SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYE. Place lens on your eye only after neutralizing the AOSEPT Disinfecting Solution and rinsing your lens thoroughly with sterile saline solution. Neutralization of AOSEPT Disinfecting Solution occurs by soaking the lenses for SIX (6) hours with the AOSEPT Disposable Cup & Disc. Do not use the AOSEPT Disposable Cup & Disc for more than 100 uses or three (3) months of daily use. Should AOSEPT Disinfecting Solution that has not been neutralized mistakenly get in your eye, REMOVE YOUR LENS IMMEDIATELY, FLUSH (WASH) YOUR EYE WITH A LARGE AMOUNT OF WATER OR STERILE SALINE for a few minutes. If burning and/or irritation persists, seek assistance from an eye care professional. Never touch the dropper tip of the bottle to any surface since this may contaminate the solution.

• DO NOT TAKE AOSEPT DISINFECTING SOLUTION INTERNALLY OR GASTRIC DISTRESS COULD RESULT. SEEK PROFESSIONAL ASSISTANCE OF A PHYSICIAN OR A POISON CONTROL CENTER IMMEDIATELY IF TAKEN INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

Follow your eye care professional'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 reactions 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 professional. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also 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 also shown that smokers have a higher incidence of adverse reactions. **IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.**

All contact lens wearers should see their eye care professional as directed. Periodic eye examinations are extremely important in order to detect and treat problems related to contact lens wear before they cause discomfort or pain.

PRECAUTIONS:

- Never reuse AOSEPT Disinfecting Solution.
- There is NO SAFE, ACCEPTABLE SUBSTITUTE IN THE AOSEPT DISINFECTION SYSTEM FOR AOSEPT DISINFECTING SOLUTION DUE TO ITS UNIQUE FORMULATION. DO NOT MIX OR SUBSTITUTE OTHER LENS CARE PRODUCTS CONTAINING HYDROGEN PEROXIDE. THESE PRODUCTS MAY NOT BE COMPATIBLE WITH AOSEPT DISINFECTING SOLUTION. DO NOT USE OVER-THE-COUNTER GENERIC HYDROGEN PEROXIDE. Generic hydrogen peroxide solutions are not intended for use with contact lenses and may contain ingredients not tested for ocular safety and/or toxicity. Generic hydrogen peroxides are not intended for ophthalmic use and will cause DISCOLORATION and DAMAGE lenses.
- NEVER USE AOSEPT Disinfecting Solution in a thermal (heat) disinfection unit.
- Store AOSEPT Disinfecting Solution at room temperature: 59° to 86°F (15° to 30°C).
- Use before the expiration date marked on the container and carton.
- To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh rinsing solution and allow to air dry.
- Keep the bottle tightly closed when not in use.
- Keep out of the reach of children.

IMPORTANT SAFETY INFORMATION

To avoid the possibility of damage to your lenses and injury from a rupturing cup, the following precautions should be taken when using the AOSEPT Disinfection System:

- **Use only AOSEPT Disinfecting Solution in the AOSEPT Disposable Cup & Disc.**
- Remember that disinfection begins upon immediate contact between AOSEPT Disinfecting Solution and the neutralizing disc.
- To prevent leaking and to ensure proper disinfection, be sure to fill the cup only to the fill line. DO NOT OVERFILL.
- To minimize the risk of contamination by your hands, avoid handling the disc.

In addition:

- DO NOT disinfect lens before thoroughly rinsing daily cleaner from surface of lens.
- DO NOT over tighten the cup (only tighten finger tight).
- DO NOT use a damaged cup.

ADVERSE REACTIONS: (Possible problems and what to do):

The following problems may occur: eyes 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 eyes, unusual eye secretions, redness of the eyes, 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 problem stops and the lenses appear to be undamaged, thoroughly clean/rinse and disinfect/ neutralize the lenses and reinsert them.
- 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 professional.
- 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 professional.

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. All adverse reactions observed while using the AOSEPT Disinfection System should be reported to: Consumer Relations, CIBA Vision Corporation, Duluth, GA 30097. 1-800-875-3001.

DIRECTIONS FOR USE WITH SOFT (HYDROPHILIC) CONTACT LENSES:

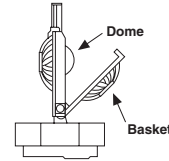
NOTE: If you are currently using a commercially available thermal (heat) disinfection system or chemical (not heat) disinfection system, the AOSEPT Disinfection System can be used interchangeably without damage to your lenses.

Clean, rinse, and disinfect/neutralize your contact lenses each time you remove them. Before handling your contact lenses, always wash your hands thoroughly and dry them with a clean, lint-free towel. To clean, rinse and disinfect/neutralize your lenses, the following two procedures must be followed:

PROCEDURE ONE—Clean your lenses after each removal.

1. Clean the surface of the right lens with MiraFlow® Extra-Strength Daily Cleaner or another recommended daily cleaner. Follow the product instructions included with the cleaner.
2. Rinse the lens thoroughly with a steady stream of sterile saline solution such as SoftWear® Saline and place the right lens on the dome in the appropriate side of the lens holder. (See note below).
3. Repeat steps one and two with the left lens and place the lens on the other dome of the lens holder.

NOTE: To prevent damage to your lens, center the lens on the dome in the lens holder. Be sure the lens does not touch the basket rim, then close the basket lid.



PROCEDURE TWO—Disinfect/neutralize your lenses AFTER steps 1-3 above have been completed.

1. You must use AOSEPT Disinfecting Solution and AOSEPT Disposable Cup & Disc for disinfection and neutralization.

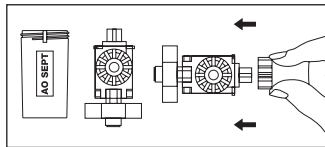
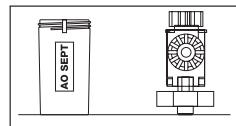
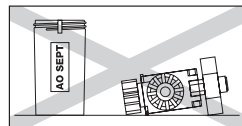


FIGURE A

2. After you've placed your lenses in the lens holder, fill the cup with AOSEPT Disinfecting Solution to the fill line and place the lens holder in the cup. Tighten (turn clockwise) the cap. DO NOT OVERFILL. Overfilling the cup will cause AOSEPT Disinfecting Solution to overflow from the cup.
3. Allow the lenses to **soak for a minimum of six (6) hours or overnight**. After a minimum of six (6) hours, your lenses are disinfected/neutralized. **If your lenses have been soaking in the cup for more than 24 hours, you must repeat the disinfection/neutralization procedure again before wearing your lenses.**
4. You must rinse each lens thoroughly with a sterile saline such as SoftWear® Saline prior to lens insertion on the eye.
5. After putting your lenses on, always discard the neutralized AOSEPT Disinfecting Solution from the lens cup, rinse with AOSEPT Disinfecting Solution or SoftWear® Saline and **leave the cup open to air dry**. This rinsing and air drying will help to keep your cup free of microbial contaminants. The lens holder should be inverted (outside the cup) so it's not lying on its side, as shown below.



CORRECT WAY



WRONG WAY

REPLACEMENT SCHEDULE:

- The AOSEPT Disposable Cup & Disc must be replaced after 100 uses or three (3) months of daily use.
- To minimize the risk of microbial contamination of the AOSEPT Lens Cup, it is recommended that you replace your AOSEPT Lens Cup every six (6) months.

DIRECTION NOTES:

- If bubbles leak from the hole on the top of the cap of the lens holder, this indicates that you have overfilled the cup or that you may not have thoroughly rinsed the cleaner off your lenses.
- Never rinse your lenses in AOSEPT Disinfecting Solution and put directly on the eye.
- **Lenses must always be disinfected/ neutralized for a minimum of six (6) hours in the AOSEPT Disposable Cup & Disc and rinsed with fresh saline before putting your lenses on.**

ENZYME CLEANING:

Enzyme cleaning is optional, based on your eye care professional's recommendation. Unizyme® Enzymatic Cleaner is recommended for use with the AOSEPT Disinfection System. See the Unizyme® Enzymatic Cleaner package insert for complete instructions.

HOW SUPPLIED: AOSEPT Disinfecting Solution is supplied sterile in 4 fl. oz. (120ml), 8 fl. oz. (237 ml), 12 fl. oz. (355ml), and 16 fl. oz. (480 ml) plastic bottles. Bottles and cartons are marked with lot number and expiration date.

All system replacement products are sold separately.

For information regarding this product, consult your eye care professional or write to: Consumer Relations, CIBA Vision Corporation, Duluth, GA 30097.

1-800-875-3001

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Made in Canada

Mfd. for: CIBA Vision Corporation,

Duluth, GA 30097 U.S.A.

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