

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

Oxysept®

**UltraCare®
Formula**

UltraCare® Formula with color indicator neutralizing tablets

A disinfecting, neutralizing and storage system for soft (hydrophilic) contact lenses, including daily and extended wear in a chemical (not heat) lens care system. Included in the Oxysept® System is Oxysept® Disinfecting Solution/Neutralizer.

Oxysept® Disinfecting Solution/Neutralizer consists of:

- Oxysept® Disinfecting Solution - a sterile 3% hydrogen peroxide solution for lens disinfection.
- Oxysept® Neutralizing Tablets - a delayed-release neutralizing tablet that is added at the beginning of the disinfection cycle, and colors the solution pink to show that the tablet has been added. This tablet allows disinfection to occur before neutralizing the solution all in one easy step.
- Oxysept® Cup - a specially designed lens cup that must be used with this system.

DESCRIPTION (INGREDIENTS)

- Oxysept® Disinfecting Solution is a sterile solution that contains micro-filtered hydrogen peroxide 3% (stabilized with sodium stannate and sodium nitrate, and buffered with phosphates) and purified water.
- Oxysept® Neutralizing Tablets are smooth, round, pink to grayish purple tablets that contain catalase, hydroxypropyl methylcellulose, and cyanocobalamin (vitamin B12) as color indicator, with buffering and tableting agents.
- Oxysept® Cup is a specially designed lens cup that must be used with this system. It consists of a single cup and a lens holder attached to the cap. The cap and left lens basket are blue. This will distinguish this cup from other lens cases.

ACTIONS

- Oxysept® Disinfecting Solution destroys and prevents the growth of harmful microorganisms on the surface of the lenses.
- Oxysept® Neutralizing Tablets turn the solution light pink and, in a delayed-release manner, neutralizes the Oxysept® Disinfecting Solution after disinfection occurs.
- Oxysept® Cup is a specially designed cup that must be used with this system for proper disinfection, neutralization and storage.

INDICATIONS (USES)

Use Oxysept® Disinfecting Solution/Neutralizer to disinfect, neutralize and store your soft (hydrophilic) contact lenses.

- Use Oxysept® Disinfecting Solution to destroy harmful microorganisms that may cause infections.
- Use Oxysept® Neutralizing Tablets to neutralize the Oxysept® Disinfecting Solution. Oxysept® Neutralizing Tablets are added at the beginning of the disinfection cycle so that disinfection and neutralization occur without any additional steps.
- Use the Oxysept® Cup to hold the lenses during disinfection, neutralization and storage.

***NOTE:** This product is not recommended for use with ILLUSIONS® (teflon) lenses. Use of this product may cause lens damage.

CONTRAINDICATIONS (REASONS NOT TO USE)

If you are allergic to any ingredient in Oxysept® Disinfecting Solution/Neutralizer, do not use this system.

WARNINGS

- KEEP Oxysept® Disinfecting Solution (HYDROGEN PEROXIDE) OUT OF THE EYES. The red tip is to remind you not to put this product in your eyes. ALWAYS USE AN Oxysept® Neutralizing Tablet WITH Oxysept® Disinfecting Solution TO NEUTRALIZE YOUR LENSES BEFORE APPLYING THEM TO YOUR EYES. If Oxysept® Disinfecting Solution accidentally comes in contact with the eyes, it may cause burning, stinging or redness. Immediately flush your eyes with water and remove the lenses. If burning or irritation continues, seek professional assistance.
- Do not crush the Oxysept® Neutralizing Tablet. If a crack occurs in the coating, the tablet may begin to neutralize the Oxysept® Disinfecting Solution before adequate disinfection occurs.
- The Oxysept® Cup is specially designed with a shortened lens holder to allow room for the Oxysept® Neutralizing Tablet at the bottom of the cup. The cap and left lens basket of the Oxysept® Cup are blue for identification of the correct cup. Use only this cup as other lens cases may not allow enough room for the tablet. Replace your Oxysept® Cup every six months or more frequently as recommended by your eye care professional.
- Keep Oxysept® Disinfecting Solution out of the reach of children. If accidentally swallowed, an upset stomach and vomiting may result. Seek immediate professional medical assistance or contact a poison control center.

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 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 that 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 had a higher incidence of adverse reactions. It is recommended that contact lens wearers see their eye care professional twice each year, or if directed, more frequently.

To avoid contamination, do not touch the tip of the Oxysept® Disinfecting Solution to any surface. Replace cap after using.

PRECAUTIONS

- Always wash, rinse and dry hands with a lint-free towel before handling lenses.
- Always clean, disinfect and neutralize your lenses each time they are removed.
- If the blister card appears damaged in any way, DO NOT USE any tablet from that card. Use a tablet from another card to neutralize the peroxide.
- Use only Oxysept® Disinfecting Solution/Neutralizer components; do not substitute.
- Never reuse solutions.
- Do not use tablets that appear to be broken or chipped.
- Always ensure that the tablet has fully dissolved and that bubbling has stopped before putting your lenses into your eyes. If the tablet has not dissolved fully, repeat the disinfection and neutralization stages.
- Do not take tablets internally.
- After reapplying your lenses, always empty the Oxysept® Cup, rinse with sterile saline solution, and allow to air dry.
- Store solutions and tablets at room temperature.
- Use before the expiration date marked on the bottle, blister card and cartons.
- Never use Oxysept® Disinfecting Solution or Oxysept® Neutralizing Tablets in a heat disinfection unit as these products are not designed for use with heat disinfection.

- Do not rinse your contact lenses or the Oxysept(R) Cup with tap water.
- Do not use the Oxysept(R) Cup if visibly dirty or moldy.

ADVERSE REACTIONS AND WHAT TO DO

The following 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
- Sensitivity to light
- Dry eyes

If you notice any of the above symptoms, IMMEDIATELY remove and examine your lenses. If a lens appears to be damaged, do not reapply; consult your eye care professional.

If the symptom stops and the lenses appear to be undamaged, follow the complete "Directions for Use", below, before reapplying them. If the symptom continues, IMMEDIATELY remove your lenses, discontinue use of all lens care products that contact the eye, 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 obtain treatment, if necessary, to avoid serious eye damage.

DIRECTIONS FOR USE

Follow the instructions below each time you remove your contact lenses. Always wash, rinse and dry hands with a lint-free towel before handling contact lenses. Always remove the same lens first to avoid mix-ups.

1. Clean and Rinse Your Lenses

Remove and handle one lens at a time. Gently rub each lens with an appropriate daily cleaner. Rinse thoroughly with sterile saline solution. Place the lens in the appropriate basket of the lens holder attached to the cap and close the basket lid. For easy identification, the left lens basket is blue.

2. Disinfect and Neutralize Your Lenses

Fill the Oxysept® Cup to the fill line with Oxysept® Disinfecting Solution. With dry hands, remove one Oxysept® Neutralizing Tablet from the blister card, drop into the solution and immediately place the lens holder containing the lenses into the Oxysept® Cup. Tighten the cap.

Gently turn the Oxysept® Cup upside down, then right side up 3 consecutive times to wet the upper surfaces of the cup and the inside of the cap. Make sure that the tablet is in the solution. The Oxysept® Neutralizing Tablet will color the solution pink. This is normal and expected. The pink coloration provides an easy visual reminder that you have added your neutralizing tablet. The color does not indicate that your lenses are neutralized or ready to wear. You must still soak your lenses for a minimum of 6 hours after the addition

of the Oxysept® Neutralizing Tablet. You will see a few bubbles or some light bubbling. If the tablet immediately begins to bubble vigorously, causing foam to form on the solution surface, the tablet is neutralizing the solution too quickly for disinfection to take place. Discard the solution and tablet, fill the cup with fresh solution, add another tablet and immediately tighten the cap. Allow the lenses to soak for a minimum of 6 hours to overnight.

The delayed-release Oxysept® Neutralizing Tablet will allow disinfection to occur before it neutralizes the solution. During the neutralization process, the tablet will begin to bubble vigorously and will completely dissolve. If the solution is not pink, you have not added an Oxysept® Neutralizing tablet to the solution.

Note: In clinical studies a small percentage of patients reported that their lenses appeared slightly pink. This temporary lens coloration does not damage your lenses, and washes away shortly after lens application.

3. Wear

Before removing lenses from the lens case, turn the lens case upside down, to ensure full neutralization of all residual disinfecting solution in the lens case.

Then apply the

lenses directly to your eyes. If desired, rinse your lenses with sterile saline solution, before lens application. Do not use Oxysept® Disinfecting Solution (hydrogen peroxide)

to rinse your lenses before wearing.

If you do not intend to wear your lenses immediately after disinfection/neutralization, you may store them in the unopened Oxysept® Cup. Disinfect and neutralize with fresh solution once a week and before applying the lenses to your eyes.

To prevent contamination and to help avoid serious eye injury, always empty and rinse cup with sterile rinsing solution and allow to air dry. Once a week, while you are wearing your lenses, fill the Oxysept® Cup with fresh Oxysept® Disinfecting Solution (do not add an Oxysept® Neutralizing Tablet). Tighten the cap. Turn the cup upside down to allow the solution to cover the inside of the cap and the top part of the cup. Leave the cup in this position until you are ready to remove your lenses from your eyes and disinfect.

Note: Once a week, simply add an Ultrazyme® Enzymatic Cleaner tablet to the Oxysept® Disinfecting Solution at the same time that you add the Oxysept® Neutralizing Tablet.

You will simultaneously reduce the buildup of protein on your soft (hydrophilic) contact lenses as you disinfect and neutralize them. For more information, see the Ultrazyme® Enzymatic Cleaner package insert, or ask your eye care professional.

HOW SUPPLIED

Oxysept® Disinfecting Solution/Neutralizer is supplied in a package containing a 12 fl oz bottle of Oxysept® Disinfecting Solution, 36 Oxysept® Neutralizing Tablets and an Oxysept® Cup.

The bottle, blister cards and carton are marked with lot number and expiration date. Store Oxysept® Disinfecting Solution, Oxysept® Neutralizing Tablets at room temperature.

LENSES

Oxysept® Disinfecting Solution/ Neutralizer is for use with soft (hydrophilic) contact lenses.