

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

Ultrazyme®

Enzymatic Cleaner

For use with soft (hydrophilic) contact lenses in combination with **OXYSEPT®** Disinfecting Solution and other* (see instructions at the end of this insert) 3% hydrogen peroxide disinfecting solutions.

DESCRIPTION (INGREDIENTS)

ULTRAZYME® Enzymatic Cleaner is an effervescent, smooth, round, white tablet that contains the enzyme subtilisin A, with effervescing, buffering and tableting agents.

ACTIONS

ULTRAZYME® Enzymatic Cleaner, dissolved in **OXYSEPT®** Disinfecting Solution or other* 3% hydrogen peroxide disinfecting solutions, simultaneously removes protein deposits while lenses are being disinfected. When used as directed, one **ULTRAZYME®** Enzymatic Cleaner tablet safely and effectively removes protein and reduces its buildup on your lenses while enhancing the disinfection capability of your hydrogen peroxide disinfecting solution.

INDICATIONS (USES)

ULTRAZYME® Enzymatic Cleaner is indicated for use in a recommended 3% hydrogen peroxide disinfecting solution such as **OXYSEPT®** Disinfecting Solution, to remove protein and reduce its buildup on soft (hydrophilic) contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use **ULTRAZYME®** Enzymatic Cleaner tablets if you are allergic to the enzyme subtilisin A.

WARNINGS

- After the enzymatic/disinfection and neutralization cycles, **lenses must be gently rubbed and rinsed with an appropriate rinsing solution before applying to your eyes.**
- **KEEP THE ENZYMATIC/DISINFECTING SOLUTION OUT OF YOUR EYES.** If the solution accidentally comes in contact with eyes, it may cause burning, stinging or redness. Immediately remove your lenses and flush your eyes with water. If burning or irritation continues, seek professional assistance.
- **ALL ENZYMATIC/DISINFECTION, NEUTRALIZATION AND RINSING CYCLES MUST BE COMPLETED BEFORE REAPPLYING YOUR LENSES.**

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 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 had 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.

It is recommended that contact lens wearers see their eye care professional once a year or if directed, more frequently.

PRECAUTIONS

- KEEP OUT OF THE REACH OF CHILDREN.
- Always wash, rinse, and dry hands before handling lenses.
- Use the lens case recommended for your disinfection system.
- Never interchange or reuse solutions.
- Do not use tablets that are soft and sticky or irregular in appearance.
- Do not take tablets internally.
- The weekly enzymatic/disinfection cycle is not a substitute for cleaning and disinfecting.
- After reapplying your lenses, always empty the lens case, rinse with sterile saline solution, and allow to air dry.
- Use before the expiration date on the tablet strip and carton.
- Never use **ULTRAZYME®** Enzymatic Cleaner in a heat disinfection unit as this product is not designed for use with heat disinfection.
- Store at room temperature, 15° -30°C (59° -86°F), in a dry place.

ADVERSE REACTIONS (POSSIBLE 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
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above problems, **IMMEDIATELY** remove and examine your lenses. If a lens appears to be damaged, do not reapply; consult your eye care professional. If the problem stops and your lenses appear to be undamaged, thoroughly clean, rinse and disinfect the lenses; then reapply. If the problem 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. Immediately remove your lenses and seek immediate professional identification of the problem, and obtain treatment, if necessary, to avoid serious eye damage. For more information, see your Instructions for Wearers booklet for your specific contact lens type.

DIRECTIONS FOR USE WITH THE OXYSEPT® SYSTEM

Use **ULTRAZYME®** Enzymatic Cleaner once a week or more often as recommended by your eye care professional.

Always wash, rinse and dry your hands before handling contact lenses. Always remove the same lens first to avoid mix-ups.

Follow the directions below each time you use the **ULTRAZYME®** Enzymatic Cleaner tablet with the **OXYSEPT®** System.

- Use only the **OXYSEPT® Cup** with the blue left lens basket for weekly enzymatic cleaning/disinfection and neutralization. Do not substitute any other lens case.
- Use only **OXYSEPT®** Disinfecting Solution/Neutralizer components. Do not substitute.

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 a sterile saline solution. Place the lens in the appropriate basket of the **OXYSEPT® Cup** lens holder.

2. DISINFECT, ENZYMATICALLY CLEAN AND NEUTRALIZE

Fill the **OXYSEPT® Cup** to the fill line with **OXYSEPT®** Disinfecting Solution. Drop one **ULTRAZYME®** Enzymatic Cleaner tablet into the solution. Then drop one **OXYSEPT®** Neutralizing tablet into the solution. **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. Allow the lenses to soak for a minimum of 6 hours to overnight.

3. RUB, RINSE AND 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. When you are ready to wear your lenses, remove one lens at a time and gently rub and rinse thoroughly with an appropriate sterile rinsing solution, then apply lenses.

To prevent contamination and to help avoid serious eye injury, always empty and rinse lens cup with sterile rinsing solution and allow to air dry.

DIRECTIONS FOR OTHER 3% HYDROGEN PEROXIDE SYSTEMS SUCH AS:

(AOSept®)

Follow the directions for your particular disinfection system. Use the lens case designed for use with your 3% hydrogen peroxide disinfecting solution.

- Place one (1) **ULTRAZYME®** Enzymatic Cleaner tablet in your 3% hydrogen peroxide disinfecting solution.
- Allow lenses to soak as usual in your disinfecting solution. However, if your disinfecting solution calls for a disinfection soak time less than 15 minutes, **increase the soak time to a minimum of 15 minutes when using ULTRAZYME® Enzymatic Cleaner**. Increasing the soak time up to a maximum of overnight will allow for increased protein removal. Consult your eye care professional to determine the best soak time for you, as individuals vary in the amount of protein they deposit.

NOTE: FAILURE TO FOLLOW THE INSTRUCTIONS SPECIFIED FOR YOUR HYDROGEN PEROXIDE DISINFECTING SOLUTION MAY RESULT IN SERIOUS EYE INFECTION. THE MINIMUM SOAK TIME WITH ULTRAZYME® ENZYMATIC CLEANER SHOULD NEVER BE LESS THAN THE MINIMUM RECOMMENDED DISINFECTION SOAK TIME FOR YOUR HYDROGEN PEROXIDE DISINFECTING SOLUTION.

- After your lenses have been enzymatically cleaned/disinfected and neutralized (following the directions for your particular disinfection system), they **must be gently rubbed** and rinsed with an appropriate sterile rinsing solution before wearing.

HOW SUPPLIED

ULTRAZYME® Enzymatic Cleaner is supplied in packages of 10 and 20 tablets. The tablet strips and cartons are marked with lot number and expiration date.

LENSES

ULTRAZYME® Enzymatic Cleaner is for use with soft (hydrophilic) contact lenses.

PRODUCT OF INDIA

Manufactured for:
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