Proclear EP Multifocal

This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

INDICATIONS (USES):

- Multifocal: Proclear EP Multifocal (omafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not aphakic persons with non-diseased corneas. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

- Proclear EP Multifocal (Omafilcon A) Soft Hydrophilic Contact lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they are removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

CONTRAINDICATIONS (REASONS NOT TO USE):

- Never use solutions recommended for conventional labeling for use in both heat and chemical disinfection.
- Never use solutions recommended for conventional hard contact lenses only.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Never use solutions recommended for conventional soft contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Do not follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for 60% EP Multifocal Contact Lenses and those prescribed by the eyecare practitioner.
- Always use FRESH unexpired lens care solutions.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- To prevent your lenses from becoming dry (dehydrated), always store your lenses completely immersed in the recommended storage solution when the lenses are not being worn. Follow the lens care directions for Care for a Dried Out Lens if your lens surface does become dry (dehydrated).
- If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens. The lens must move freely on the eye for continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always handle lenses carefully and avoid dropping them.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always inform the doctor (health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in or on your eyes.
- Always inform employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that patient not wear contact lenses.

Aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled. Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye. Do not follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for 60% EP Multifocal Contact Lenses and those prescribed by the eyecare practitioner. Always use FRESH unexpired lens care solutions. Never wear lenses beyond the period recommended by the eyecare practitioner. Do not use saliva or anything other than the recommended solutions to wet your lenses. To prevent your lenses from becoming dry (dehydrated), always store your lenses completely immersed in the recommended storage solution when the lenses are not being worn. Follow the lens care directions for Care for a Dried Out Lens if your lens surface does become dry (dehydrated). If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens. The lens must move freely on the eye for continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner. Avoid all harmful or irritating vapors and fumes while wearing your lenses. Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand. Do not touch the lens with fingernails. Always handle lenses carefully and avoid dropping them. Ask the eyecare practitioner about wearing lenses during sporting activities. Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner. Always inform the doctor (health care practitioner) that you wear contact lenses. Always consult your eye care practitioner before using any medicine in or on your eyes. Always inform employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that patient not wear contact lenses.
As with any contact lens, follow-up visits are necessary to assure health. Patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS: The patient should be informed that the following problems may occur:

- Eyes sting, burn, or itch (irritation) or other eye pain
- Comfort is less than when lenses were first placed on eye
- Feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye sensations
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbow arcs around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- IMMEDIATELY REMOVE LENSES

- If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or another foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lens; then reinsert them. If the problem continues, DO NOT put the lens back on your eye; immediately consult an eye care practitioner.

WHEN ANY OF THE ABOVE SYMPTOMS OCCUR, A SERIOUS CONDITION SUCH AS INFECTION, ABRASION, CORNEAL ULCE, NEOVASCULARIZATION, OR IRITIS MAY BE PRESENT. The patient should be instructed to immediately seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING: Conventional methods of fitting contact lenses apply to these soft contact lenses. For a detailed description of the fitting technique, refer to the “Selection of Patient’s” section in the Professional Fitting Guide, copies of which are available from CooperVision, Inc.

LENSES CARE DIRECTIONS:

Eycare practitioners should review with the patient lens care directions and specific lens care information and specific instructions on the lens care regimen recommended for the patient. The lenses may be disinfected using either a hydrogen peroxide disinfection system as recommended by the eyecare practitioner.

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use a lens cleaning solution, even if lenses appear clean.
- Use the recommended system of lens care and carefully follow instructions on solution labeling.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solution for lubricating or rewetting lenses.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse and disinfect lenses.
- The eyecare practitioner should recommend a care system that is appropriate for the 60% EP Multifocal Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- Note: Some solutions may have more than one function which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case.
- After cleaning, disinfect your lenses using the system recommended by the eyecare practitioner.
- To store lenses, disinfekt and leave them in the closed unopened case until ready to wear. If lenses are not to be used immediately, follow disinfection procedure. The patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty the used lens care solution into the lens care container, then allow the lens case to air dry. When the case is used again, refill it with the lens care solution as recommended by the lens care manufacturer. If the lens case is not used, the patient should immediately consult an eye care practitioner.

Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfection solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PRACTITIONER.

WEARING SCHEDULE: The wearing schedule should be determined by the eye care practitioner. Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regimens, as determined by the eye care practitioner, also are extremely important.

60% EP Multifocal Contact Lenses are indicated for Daily Wear. The maximum suggested wearing time for these soft contact lenses is:

<table>
<thead>
<tr>
<th>Days</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours**</td>
<td>6</td>
<td>6</td>
<td>8</td>
<td>8</td>
</tr>
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While patients who experience discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren’s only) may wear these lenses with improved comfort compared to other soft (hydrophilic) contact lenses, their wearing time may be less than it would if they did not have dry eye symptoms.

Studies have not been conducted to show that these soft contact lenses are safe to wear during sleep. Soft contact lenses are safe to wear during sleep.

When using hydrogen peroxide lens care systems, lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may irritate to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

Base line values for comfort with pre-study lenses ranged between 6 and 6.7 on the 10 point scale. 32% of patients found their existing lenses to be comfortable at the end of the day. The values for Proclear® was statistically different compared to the baseline values collected from the control lenses. As in this study, individual results may vary.


DO NOT USE IF THE BLISTER PACK HAS BEEN DAMAGED OR BROKEN

REPORTING OF ADVERSE REACTIONS: All serious adverse experiences and adverse reaction observations in patients wearing 60% EP Multifocal Contact Lenses or experienced with the lenses should be reported to:

Attn: Regulatory Affairs
711 North Road
Scottsville, NY 14546
1-800-341-2020

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