PROCLEAR (omafilcon A)  
Soft (Hydrophilic) Contact Lenses 
Daily Wear 
For Planned Replacement or Daily Disposable 

Part Number PI014F  
May 2012  

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lens.

SYMBOLS KEY:  
The following symbols may appear on the label or carton.

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DEFINITION</th>
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<td>Rx only</td>
<td>Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner</td>
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<td>See Instructions for Wearers</td>
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CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION

PROCLEAR (omafilcon A) Contact Lenses are available as spheric, aspheric, toric and multifocal lens designs. The lenses are made of polymer of 2-hydroxyethylmethacrylate and 2-methacryloxyethyl phosphorylcholine cross-linked with ethyleneglycol dimethacrylate. The lens material has a permanent tint using color additive Reactive Blue 4 or Vat Blue 6.

PROCLEAR SPHERE contact lenses parameters:
- Diameter: 14.2mm
- Base Curve: 8.2, 8.6
- Center Thickness: 0.065 mm to 0.35 mm (varies with power)
- Powers: –20.00D to +20.00D in (0.50 D steps after +/-6.50 D)

PROCLEAR TORIC contact lenses parameters:
- Diameter: 14.4mm
- Base Curve: 8.4, 8.8
- Center Thickness: 0.07mm to 0.35mm (varies with power)
- Powers: +6.00 to –8.00 (0.50 D steps above -6.50 D)
- Cylinder: –0.75, or -1.25, or -1.75, or -2.25 D
- Axis: 10° to 180° in 10° increments with ANSI standards

PROCLEAR MULTIFOCAL contact lenses parameters:
- Diameter: 14.4mm
- Base Curve: 8.70
- Center Thickness: 0.15 to 0.35 mm (varies with power)
- Powers: +4.00 to -6.00 D in 0.25 D steps
- Addition Powers: +1.00, +1.50, +2.00, or +2.50 D

PROCLEAR MULTIFOCAL XR contact lenses parameters:
- Diameter: 14.4mm
- Base Curve: 8.4, 8.70
- Center Thickness: 0.15 to 0.35 mm (varies with power)
- Powers: +20.00 to -20.00 D in (0.50 D steps after +/- 6.50 D)
- Addition Powers: +1.00, +1.50, +2.00, +2.50, +3.00, +3.50, or +4.00 D

The physical/optical properties of the lenses are:
- Refractive Index: 1.387
- Light Transmittance: >90%
- Surface Character: Hydrophilic
- Water Content: 62%
- Specific Gravity: 1.76
- Oxygen Permeability: Guard Ring Edge Corrected 27 x 10⁻¹¹ Boundary Layer Corrected*34 x 10⁻¹¹

Call our Customer Service Department at (800) 341-2020 for current availability

ACTIONS

When placed on the cornea in its hydrated state, the PROCLEAR (omafilcon A) Soft (Hydrophilic) Contact Lenses acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS FOR USE

Spherical

PROCLEAR (omafilcon A) SPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00D to +20.00D dipters. The lenses may be worn by persons who exhibit astigmatism of -2.00 dipters or less that does not interfere with visual acuity.

Toric

PROCLEAR (omafilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from –20.00 to +20.00 dipters and astigmatic corrections from –0.25 to –10.00 dipters.

Multifocal and Multifocal XR

PROCLEAR (omafilcon A) multifocal and multifocal XR lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 dipters or less that does not interfere with visual acuity.

The PROCLEAR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. As prescribed for single use daily disposable wear, patients are instructed to dispose of the lens at each removal. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use soft contact lenses when any of the following conditions exist:
- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoaesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution, which is to be used to care for any soft contact lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

**WARNINGS**

Patients should be advised of the following warnings pertaining to contact lens wear:

- **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION.** It is essential that you follow your eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case.

  You should fill your lens case with fresh solution every time you store your lenses and never “top-off” or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case. You should not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled or distilled, or with any non-sterile solution.

  Clean, rinse and air-dry your lens case each time you remove your lenses. In order to permit excess solution to drain, you can flip over your lens case while air drying. Replace your lens case frequently, depending upon your hygiene habits.

  The results of a study indicate the following:

  a. The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.

  b. The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.

  c. When daily users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.

  d. The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

  e. The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

  f. If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Practitioner. It is recommended that contact lens users see their Eye Care Practitioner routinely as directed.

**PRECAUTIONS**

**Special Precautions for Eye Care Practitioners**

- Due to the small numbers of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

- The potential impact of these factors on the patient’s ocular health should be carefully weighed against the patient’s need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Aphakic patients should not be fitted with any soft contact lenses until the determination is made that the eye has healed completely.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Before leaving the eye care practitioner’s office, the patient should be able to prompt remove the lenses or should have someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

**Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:**

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.

- Never use solutions recommended for conventional hard 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 use fresh unexpired lens care solutions.

- Always follow directions in the package inserts for the use of contact lens solutions.

- Use only a chemical lens care system. Use of a heat care system can damage the soft contact lenses.

- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

- Always keep lens completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage lenses and reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.

- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions in the Patient Instructions for soft contact lenses and those prescribed by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.

- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses gently and avoid dropping them.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eye care practitioner about wearing the lenses during sporting activities.

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New England Journal of Medicine, September 21, 1989; 321(12), pp. 773-783
treatment to avoid serious eye damage.

The patient should be instructed to seek immediate care if any of the following problems occur:

- Sensitivity to light (photophobia).
- Blurred vision, rainbows, or halos around objects.
- Reduced sharpness of vision (poor visual acuity).
- Excessive tearing of the eyes.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Ears stinging, burning, or itching (irritation), or other ear pain.
- Headache.
- Nausea.
- Vomiting.
- Fever.
- Rash.
- Swelling of an eyelid.
- Swelling of the face.
- Vision changes.
- Changes in color vision.
- Changes in accommodation.
- Changes in color appearance.
- Changes in visual acuity.
- Changes in visual field.
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lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

**CHEMICAL LENS DISINFECT** (Including Hydrogen Peroxide):

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning** and rinsing, to **disinfect**, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses must be **neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat** the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **CAUTION:** Lenses that are chemically disinfected may absorb ingredients from the disinfesting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.

**LENS CASE CLEANING AND MAINTENANCE**

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

**CARE FOR A DRIED OUT (DEHYDRATED) LENS**

If any soft contact lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

**CARE FOR A STICKING (NONMOVING) LENS**

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues more than 5 minutes, the patient should immediately consult the eye care practitioner.

**EMERGENCIES**

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**HOW SUPPLIED**

Each lens is supplied sterile in a buffered saline solution. The container is labeled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

**DO NOT USE IF THE CONTAINER IS BROKEN OR THE SEAL HAS BEEN DAMAGED**

**REPORTING OF ADVERSE REACTIONS**

All serious adverse experiences and adverse reactions observed in patients wearing any soft contact lens or experienced with the lenses should be reported to:

![CooperVision](https://www.coopervision.com)

Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

Juana Diaz, PR 00795