

Package Insert



CooperVision™

Proclear Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear

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

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:

SYMBOL	DEFINITION
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat

Description:

Proclear Multifocal Toric (omafilcon A) Contact Lenses are available as toric lens designs.

The lenses are made from a material containing 59% water and 41% omafilcon A, a polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with the color additive C. I. Reactive Blue 4 or permanently fixed with VAT Blue #6.

The front surface of the Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic. The Proclear Multifocal Toric contact lenses are designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

The Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are available in two versions. The **Proclear Multifocal Toric (D)** with a spherical central zone for the correction of distance

vision and an aspherical annular zone for the correction of intermediate and near vision. The **Proclear Multifocal Toric (N) with** a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision. Both lenses are a flexible transparent hemispherical shell of the following dimensions:

- Chord Diameter: 14.4 mm
- Center Thickness (minus): 0.09 mm to 0.65 mm (varies with power)
- Base Curve: 8.3 mm to 8.9mm
- Spherical Powers: -20.00 D to +20.00 D (0.50 steps)
- Cylinder Powers: -0.75 to -3.00 D
- Add Powers: +1.00 to +4.00
- Central Zone Diameter: 2.3 mm to 2.6 mm (D)
1.7 mm to 2.0 mm (N)

The physical properties of the lenses are:

Refractive Index at 25° C	1.395 ± 0.005
Light Transmittance	>90%
Water Content	59 %
Oxygen Permeability*	21.05 x 10 ⁻¹¹ <i>*(cm²/sec) (ml O₂/ml x mm Hg) at 35° C. as measured by 201T Permeometer connected to a curved Rehder guard ring polarographic cell.</i>

Actions:

In its hydrated state, the Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lens when placed on the cornea 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 (USES):

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic in powers from -20.00 to 20.00, possess astigmatism to -5.75 diopters, and are presbyopic. The 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 the eye care practitioner in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients 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):

DO NOT USE this contact lens when any of the following conditions exist:

- Previously diagnosed primary Sjogren's Syndrome Tear Deficiency, Autoimmune connective tissue disease which may involve secondary Sjogren's syndrome. Such conditions include rheumatoid arthritis, polyarthritis, Wegener's granulomatosis, systemic lupus erythematosus, systemic sclerosis, primary biliary cirrhosis, and mixed connective tissue disease.
- Acute and subacute inflammation between the lens, iris, and cornea, i.e., 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).
- Any active corneal infection: purulent (pus) bacterial, fungal, or viral infection.
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease, which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- 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 were not studied who exceed the conditions characterized by any of the following diagnostic parameters:

- Rose Bengal staining > 12 on a scale of 18
- Fluorescein staining >12 on a scale of 15
- Meibomian gland dysfunction >3 on a scale of 0-4

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 follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect your lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean your lenses.

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 result of a study¹ 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 are 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 wears see their Eye Care Practitioner routinely as directed.

¹NewEnglandJournalofMedicine, September 21, 1989; 321(12), pp. 773-783

PRECAUTIONS: Special Precautions for Eye Care Practitioners:

Due to the small number of patients enrolled in clinical investigation 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 on-eye lens dehydration, 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 this dye and become discolored. Whenever fluorescein is used in 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 promptly remove lenses easily or should have someone else available to 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 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 while are used 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.
- Always 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 the Proclear Multifocal Toric Contact Lens and those prescribed by the eye care practitioner.
- Always use FRESH unexpired lens care solutions.
- Never wear lenses beyond the period recommended by the eye care 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 keep them 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 consult his or her eye care 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.
- Bacteria can grow in contact lens cases. It is important to properly use, clean, and replace your cases, at regular intervals, recommended by the lens case manufacturer or your eye care practitioner.
- Always handle lenses carefully and avoid dropping them.

- Ask the eye care practitioner about wearing lenses during sporting activities.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always inform the doctor (health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform employer of being a contact lenses 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 lens was first placed on-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)
- 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 lens case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses; 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 ULCER, NEOVASCULARIZATION, UVEITIS, OR IRITIS MAY BE PRESENT. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting contact lenses do not apply to Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses. For a detailed description of the fitting technique, refer to the Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses Professional Fitting Guide, copies of which are available from:



CooperVision™

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711 North Road
Scottsville, NY 14546
1-800 341-2020
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WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

Daily Wear

Maximum wearing time:

Days	1	2	3	4
Hours**	4	6	8	All Waking Hours

**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.

LENS CARE DIRECTIONS:

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient: The lens may be disinfected using either a heat, peroxide or chemical disinfection system.

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 fresh unexpired lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) 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. Do not put lenses in the mouth.
- 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, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The eye care practitioner should recommend a care system that is appropriate for the Proclear Contact Lens. 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. Then repeat the procedure for the second lens.
- After cleaning, disinfect your lenses using the system recommended by eye care practitioner.
- To store lenses, disinfect and leave them in the closed unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

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 disinfecting solution in the 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 disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions 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 your eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED LENS):

If a soft contact lens is off the eye and exposed to air for 10 minutes or longer, it will become dry and brittle. Handle the lens carefully. To rewet lens: Place the lens in its storage case and SOAK the lens in the recommended rinsing and storage solution for at least one hour. Soak the lens until it returns to a soft state. Clean and disinfect the rewetted (rehydrated) lens using the lens care system recommended by eye care practitioner. If, after soaking, the lens does not become soft, DO NOT USE THE LENS, but contact eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving or cannot be removed) on the eye, apply 2-3 drops of the recommended lubricating solution directly to the eye and wait until the lens begins to move freely on eye before removing it. If non-movement of the lens continues for more than 5 minutes, the patient should immediately consult 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 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 blister pack containing buffered saline solution. The container is labeled with the base curve, diopter power (reading add power, cylinder power and axis are included) diameter, manufacturing lot number and expiration date of the lens.

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

PROVIDES ALL DAY COMFORT:

For information on the original 3 month study of lens comfort in dry eye patients, please refer to the Clinical Test Results section of the Professional Fitting and Information Guide or refer to Lemp MA *et al.* Omaficon A (Proclear) soft contact lenses in a dry-eye population. *CLAO J*, 1999; 25 (1): 40-47

A two week study of 50 subjects was conducted for the purpose of evaluating comfort and wearing time for Proclear® soft contact lenses. Comfort was measured using a 10 point scale where 0 was extremely uncomfortable and 10 was extremely comfortable. A grade was obtained for each of the following Comfort, Dryness, frequency of symptoms, overall satisfaction with existing lenses, and lens preference.

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. Study results found that the average comfort rating for Proclear® lenses was >8 out of 10. A higher proportion of the patients found Proclear lenses to be comfortable at the end of the day (91.5% found Proclear comfortable at the end of the day). The values for Proclear® were statistically different compared to the baseline values collected from the control lenses. As in this study, individual results may vary.

Reference: Hall, B. (2002). Can a Dry Eye Test Predict Soft Contact Lens Use? *Contact Lens Spectrum* August 2002

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Proclear Contact Lenses or experienced with the lenses should be reported to:



CooperVision™

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1-800-341-2030

www.coopervision.com

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REFERENCE:
NEI/Industry Workshop on Clinical Trials in Dry Eyes - CLAO October 1995