Proclear Multifocal Toric D and Proclear Multifocal N Multifocal Toric (omalcon A) Soft (Hydrophilic) Contact Lenses are 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 D and Proclear Multifocal N 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 D and Proclear Multifocal N Multifocal Toric (omalcon A) Soft (Hydrophilic) Contact Lenses are 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 D and Proclear Multifocal N 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 potential impact of these factors on the patient’s ocular health should be carefully weighed against the patient’s need to wear contact lenses.

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

- Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
- Any eye disease, including any anomaly that affects the cornea, conjunctiva, or eyelids.
- Any active corneal infection: purulent (pus) bacterial, fungal, or viral.
- Corneal hypothermia (reduced corneal sensitivity), if not-adequate.
- Any systemic disease, which may affect the eye or be exacerbated 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.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Chemical solutions disinfection 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 makeup 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 have been in contact with chemicals or the cold environment. 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 unsupervised 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 Lenses 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 the lens appears undamaged, the patient should be instructed to: IMMEDIATELY REMOVE LENSES.
- If the rose Bengal staining > 12 on a scale of 18 or fluorescein staining >12 on a scale of 15, or Meibomian gland dysfunction >3 on a scale of 0-4, patients should be advised of the following warnings pertaining to contact lens wear:
- If the lens contains any material, such as thimerosal or mercury, in a solution which must be used to care for the lens.
- If the lenses are worn overnight.
- If 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-use eye.
- 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 redness becomes reoccurring.
- Eye care practitioners should carefully advise patients that different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Non-pharmaceutical products recommended for conventional hard contact lenses only.

Adverse Reactions: The patient should be informed of the following adverse reactions:

- Eyes sting, burn, or itch (irritation) or other eye pain
- Comfort is less than when lenses was first placed on-eye
- Feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eye
- Unusual discomfort
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbow, 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 discontinuation of lenses, look closely at the lenses. If the lenses 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 lenses has dirt, any wear on the lenses, or if the lenses appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses; then reinsert the lenses. If the problem continues, DO NOT put the lens back on your eye; immediately consult an eye care practitioner.

Prolonged use of rigid lenses may result in serious injury to the eye. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.

Precautions:

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 may not be significant in numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that make the lens performance, ocular and corneal health, and on-eye lens dehydration, oxygen permeability, wettablity, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient’s ocular health should be carefully monitored by the prescribing eye care practitioner, since individual patient response may vary.

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-use eye.

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 lenses 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 the lens appears undamaged, the patient should be instructed to: IMMEDIATELY REMOVE LENSES.

If the rose Bengal staining > 12 on a scale of 18 or fluorescein staining >12 on a scale of 15, or Meibomian gland dysfunction >3 on a scale of 0-4, patients should be advised of the following warnings pertaining to contact lens wear:

- Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
- Any eye disease, including any anomaly that affects the cornea, conjunctiva, or eyelids.
- Any active corneal infection: purulent (pus) bacterial, fungal, or viral.
- Corneal hypothermia (reduced corneal sensitivity), if not-adequate.
- Any systemic disease, which may affect the eye or be exacerbated 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.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Chemical solutions disinfection 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 makeup 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 have been in contact with chemicals or the cold environment. 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 unsupervised 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 Lenses 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 lenses 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 the lens appears undamaged, the patient should be instructed to: IMMEDIATELY REMOVE LENSES.
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.

- **While patients who experience discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjögren’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.

**Lenses Care Directions**

**Basic Instructions:**

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

- **General Lens Care** (To First Clean and Rinse, Then Disinfect Lenses)
  - 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 (therma) 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.**

- **Care for a Dried Out (Dehydrated) Lens**
  - If your omaflexion A Hydrophilic Contact Lens is off your eye and exposed to air for 30 minutes or longer, it will become dry and brittle. To rewet your lens:
  - Handle the lens carefully.
  - 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 your eye care practitioner.
  - If after soaking, the lens does not become soft, DO NOT USE THE LENS, but contact your eye care practitioner.

- **Care for a Sticking Lens**
  - If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended lubricating solution. Wait until the lens begins to move freely on eye before removing it. If non-movement of the lens continues, the patient should immediately consult eye care practitioner.

- **Diagnostic Lens Care**
  - Eye care practitioners should educate contact lens technicians concerning proper care of diagnostic lenses.
  - Each contact lens is sterilized in a glass vial containing a sterile buffered isotonic saline solution. The lens is then chemically disinfected.
  - Each contact lens is sterilized in a glass vial containing a sterile buffered isotonic saline solution.
  - Maximum wearing time:
    - **30 days**
    - **40 days**
    - **60 days**
    - **90 days**
    - **All Wearing Hours**

**Chemical (Not Heat) Lens 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 regime 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 on the eye should reduce the potential for irritation.

**Reporting of Adverse Reactions**

All serious adverse experiences and adverse reactions observed in patients wearing Proclear Multifocal Toric (omaflexion A) contact lenses or experienced with the lenses should be reported to:

CooperVision, Inc.
Attn: Product Services
711 North Road
Scottsville, NY 14546
1-800-341-2020

www.coopervision.com

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**How Supplied**

Each lens is supplied in a glass vial containing buffered saline solution. The glass vial is marked with the base curve, diameter, dioptic power and reading add power, manufacturing lot number, and expiration date of the lens.

**Do Not Use If the Blister Pack is Broken Or The Seal Has Been Damaged**