

IMPORTANT

Please read carefully and keep this information for future use.

(omafilcon A)






Soft (hydrophilic) contact lenses

60% XC Aspheric

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.

SYMBOLS KEY:

The following symbols may appear on the label or carton:

Symbol	Description
	CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a licensed practitioner.
	See Instruction Leaflet
	Use by date (expiration date)
	Batch code
	Sterile using steam heat

Omafilcon A is made of polymer of 2-hydroxyethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine cross-linked with ethyleneglycol dimethacrylate. The lens material has a permanently fixed tint using color additive Reactive Blue 4.

The physical properties of the lenses are:

Refractive Index at 25° C	1.40
Light Transmittance	> 90%
Water Content	60%

Oxygen Permeability*

Coulometric method at 34°C	21 x 10 ⁻¹¹
Guard Ring Edge Corrected	**25 x 10 ⁻¹¹

*(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.

DESCRIPTION: 60% XC Aspheric (omafilcon A) Soft Hydrophilic Contact Lenses are a hemispherical shell available in the following dimensions:

o **Chord Diameter:** 14.2 mm

o **Base**

Curve:	Powers:
8.50	+0.50D to +6.00D and plano to -10.00D*

* 0.50 D steps above -6.00D

otherwise all power steps are in 0.25D increments

o **Center Thickness:** 0.075 to 0.246 mm dependent on power

ACTIONS: In its hydrated state, the soft contact lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS (USES):

60% XC Aspheric (omafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

60% XC Aspheric (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 lens 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:

- o Previously diagnosed primary Sjogren's Syndrome Tear Deficiency and 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.
- o Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
- o Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- o Any active corneal infection: purulent (pus) bacterial, fungal, or viral infection.
- o Corneal hypoaesthesia (reduced corneal sensitivity), if not-aphakic.
- o Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- o Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens.
- o Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- o If eyes become red or irritated

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 SERIOUS INJURY TO THE EYE.

It is essential that patients follow eye care practitioner's directions and all labeling instructions for proper use of 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 patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers. 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 eyecare practitioner.

PRECAUTIONS: Special Precautions for Eyecare 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 eyecare 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 eyecare 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-eye use.

- o 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.
- o Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- o Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:
- o Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- o Never use solutions recommended for conventional hard contact lenses only.
- o Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- o 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.
- o If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- o 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.
- o Always follow directions in the package inserts for the use of contact lens solutions.
- o Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- o Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for 60% XC Aspheric Contact Lens and those prescribed by the eyecare practitioner.
- o Always use FRESH unexpired lens care solutions.

- o Never wear lenses beyond the period recommended by the eyecare practitioner.
- o Do not use saliva or anything other than the recommended solutions to wet your lenses.
- o 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).
- o 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.
- o Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- o Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand.
- o Do not touch the lens with fingernails.
- o Always handle lenses carefully and avoid dropping them.
- o Ask the eyecare practitioner about wearing lenses during sporting activities.
- o Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- o Always inform the doctor (health care practitioner) that you wear contact lenses.
- o Always consult your eye care practitioner before using any medicine in your eyes.
- o 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.
- o 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:

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

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

- o 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 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, 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 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.
Attn: Regulatory Affairs
711 North Road
Scottsville, NY 14546 (USA)
1-800-341-2020
www.coopervision.com

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. Regular checkups, as determined by the eye care practitioner, also are extremely important.

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

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:

Eyecare 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 peroxide or chemical disinfection system as recommended by the eyecare practitioner.

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

Basic Instructions:

- o Always wash, rinse, and dry hands before handling contact lenses.
- o Always use fresh unexpired lens care solutions.
- o 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.

- o Do not use saliva or anything other than the recommended solution for lubricating or rewetting lenses. Do not put lenses in the mouth.
- o 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.
- o Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribe by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- o The eyecare practitioner should recommend a care system that is appropriate for the 60% XC Aspheric Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- o **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.
- o 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.
- o After cleaning, disinfect your lenses using the system recommended by eye care practitioner.
- o 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 eyecare practitioner for information on storage of lenses.
- o 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 eyecare practitioner.
- o Eyecare 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:

- o Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- o After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.
- o When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- o Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- o Do not heat the disinfection solution and lenses.

- o Leave the lenses in the unopened storage case until ready to put on the eyes.
- o **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 ENZYMIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by the eyecare 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 eyecare 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 (re-hydrated) 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 LENS - If the lens sticks (stops moving) on the eye, apply 2-3 drops of the lubricating solution recommended by the Eyecare practitioner. 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.

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 EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED – 60% XC Aspheric lenses are sterilized and supplied in a blister package containing buffered saline solution. The blister package is marked with the base curve, dioptric power, diameter, manufacturing lot number of the lens and expiration date.

*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.* Omafilcon A (Proclear) soft contact lenses in a dry-eye population. *CLAOJ*, 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

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

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing 60% XC Aspheric Contact Lenses or experienced with the lenses should be reported to:



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

Rev Date:PI0123A Mar/2007-
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REFERENCE: NEI/Industry Workshop on Clinical Trials in Dry Eyes - CLAO October 1995