

## IMPORTANT

Please read carefully and keep this information for future use.

### 60% 1-Day (omafilcon A)






Soft contact lenses for Single Use Daily Disposable.

### Sphere, Asphere, Toric and 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.

#### SYMBOLS KEY:

The following symbols may appear on the label or carton:

Symbol	Description
	<b>CAUTION:</b> 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

60% (omafilcon A) is made of 2-hydroxyethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine polymers cross-linked with ethyleneglycol dimethacrylate. The lens material has a permanently fixed tint using VAT Blue 6.

The physical properties of the lenses are:

Refractive Index at 25° C	1.40
Light Transmittance	> 90%
Water Content	60% ±2%
Oxygen Permeability*	
Polarographic FATT Method	21 x 10 <sup>-11</sup>
Modified FATT Method Guard	
Ring Edge Corrected	25 X 10 <sup>-11</sup>

\* (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml x mm Hg) at 35° C. as measured by 201T Permeometer connected to a polarographic cell.

#### DESCRIPTION:

60% 1-Day (omafilcon A) Soft (hydrophilic) Contact Lenses are a hemispherical shell available in the following dimensions:

- o Chord Diameter: 13.0 mm to 15.5 mm
- o Base Curve: 8.00 mm to 9.50 mm
- o Powers: -20.00 D to +20.00 D
- o Cylinder Powers: -0.50 D to -5.00 D as applicable
- o Axis: 1° to 180° as applicable
- o Add Power Range: +0.25 D to +5.00 D as applicable
- o Center thickness: 0.035 mm to 0.96 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):

**Sphere and Asphere:** (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-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.

**Toric:** (omafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who have astigmatism of 5.00D or less.

**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 non-aphakic persons with non-diseased eyes. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

60% 1-Day (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.

#### CONTRAINDICATIONS (REASONS NOT TO USE):

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

- o Previously diagnosed primary Sjogrens Syndrome Tear Deficiency and Autoimmune Connective Tissue Disease which may involve secondary Sjogrens 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 hypoesthesia (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 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 Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - o Carefully follow the handling, insertion, removal and wearing instructions in the Patient Instructions for these lenses and those prescribed by the eyecare practitioner.
  - 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 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 Lenses prescribed on a daily disposable wearing schedule should always be discarded when removed at the end of the wearing day.
- 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 or eye
- 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. 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**  
**1-800-341-2020**  
**www.coopervision.com**

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYECARE 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% 1-Day (omafilcon A) 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:

- o Eyecare practitioners should review with the patient that cleaning or disinfection is not needed with disposable lenses. Patients should always dispose of the lenses when they are removed and have replacement lenses or spectacles available.
- 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.

#### 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. If this should occur, the patient should discard the lens and use a new one.

#### 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** – These 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. 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

**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 these lenses should be reported to:



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

Rev Date: Aug 2019  
 Part Number: PI01116

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