












# MiSight (omafilcon A ) Soft (Hydrophilic) Contact Lenses For Single-Use Disposable Daily Wear

**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
	Manufacturer
	Authorized representative in the European Community
	Do not use if package is damaged
	Consult instructions for use / consult electronic instructions for use
	Do not re-use
	Date of manufacture

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.**

## DESCRIPTION

**MiSight** (omafilcon A) Contact Lenses are designed for myopia control and vision correction.

The lenses are made from a material containing 60% water and 40% omafilcon A, consisting of 2-hydroxy-ethylmethacrylate and 2-methacryloxyethyl phos-phorycholine polymers cross-linked with ethyleneglycol dimethacrylate. The lens material has a permanently fixed tint using Vat Blue 6, which is added to make the lens more visible for handling.

**MiSight** contact lenses parameters:

- o Diameter: 13.0mm to 15.5mm
- o Base Curve: 8.00 mm to 9.50 mm
- o Center Thickness: 0.08 mm to 0.14 mm (dependent on power)
- o Powers: -6.00D to -0.25D, +0.25 steps

The physical/optical properties of the lens are:

- o Refractive Index: 1.40 at 25 °C
- o Light Transmittance: > 90%
- o Water Content 60% ± 2%
- o Oxygen Permeability (Dk)  $21 \times 10^{-11}$  (cm<sup>2</sup>/sec) ml O<sub>2</sub>/ml x mm Hg (Polarographic FATT method):

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

## ACTIONS

When placed on the cornea in its hydrated state, the **MiSight** (omafilcon A ) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

## INDICATIONS FOR USE

MiSight (omafilcon A) Soft Contact Lenses for Myopia Control 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 +2.00 diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MiSight (omafilcon A) Soft Contact Lenses for Myopia Control may reduce the rate of myopia progression in children (6-18) and correct ametropia. Reduction of myopia progression was observed in children with wearing time of 12 hours (8-16 hours) per day, 6.4 days (5-7) per week in a clinical study. Permanent myopia control after lens treatment is discontinued is not supported by clinical studies.

MiSight (omafilcon A) Soft Contact Lenses for Myopia Control 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).

MiSight (omafilcon A) Soft Contact Lenses for Myopia Control are indicated for single use daily disposable wear. When prescribed for daily disposable wear, the lens is to be discarded after each removal.

## CONTRAINDICATIONS

Do not use the **MiSight** 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 or infection of the anterior chamber of the eye.
- o Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- o Severe insufficiency of lacrimal secretion (dry eyes).
- o Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- o Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- 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 Any active corneal infection (bacterial, fungal, or viral).
- o If eyes become red or irritated.
- o The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

## WARNINGS

**Adult supervision of children to ensure proper user compliance for lens insertion, wear and removal is recommended.**

Patients were not studied who exceed the conditions characterized by any of the following diagnostic parameters:

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

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

- o PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. Patients should be cautioned that proper use and care of the contact lenses and lens care products, including lens cases,

are essential for the safe use of these products. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. Additionally, they should clean and rinse their lens case between uses as recommended by their eye care practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.

- The result of a study<sup>1</sup> 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 wearers see their Eye Care Practitioner routinely as directed.

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

## PRECAUTIONS

### Special Precautions for Eye Care Practitioners

- Due to the small numbers 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 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.
- Aphakic patients should not be fitted with any **MiSight** 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 promptly 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:

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- 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 **MiSight** 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.
- Lenses prescribed on a daily disposable wearing schedule should always be discarded when removed at the end of the wearing day.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The 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 stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a 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 the lenses.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. If the problem continues, do not put the lens back on your eye; **immediately remove the lenses and consult the eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the 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 all **MiSight** contact lenses. For a detailed description of the fitting techniques, refer to the **MiSight** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.  
711 North Road  
Scottsville, New York 14546  
1-800-341-2020

www.coopervision.com

## WEARING SCHEDULE

**The wearing and replacement schedules should be determined by the eye care practitioner.** Patients tend to over-wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

CooperVision recommends that all **MiSight** lenses be discarded and replaced with a new lens on a daily basis.

**DAILY DISPOSABLE WEAR:** (less than 24 hours, while awake). The maximum suggested wearing time is:

DAY	Hours	Day	Hours
1	6	4	12
2	8	5	14
3	10	6	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

- The patient should always have a spare pair of lenses at all times
- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. Do not put lenses in the mouth.
- Eyecare practitioner 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.
- 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 any **MiSight** 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.**

## \*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

## HOW SUPPLIED

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

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

## REPORTING OF ADVERSE REACTIONS

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



CooperVision

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

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