



CooperVision®

MiSight® 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses For 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	Reference
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1, Symbol 5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult instructions for use / consult electronic instructions for use	BS EN ISO 15223-1 Table 1, Symbol 5.4.3
	Do not re-use	BS EN ISO 15223-1 Table 1, Symbol 5.4.2
	Date of manufacture	BS EN ISO 15223-1 Table 1, Symbol 5.1.3

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

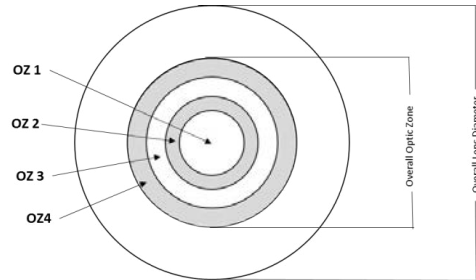
DESCRIPTION

MiSight (omafilcon A) daily wear single use contact lenses are made from a material containing 60% water and 40% omafilcon A, consisting of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl 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 daily wear single use contact lenses parameters:

- o Diameter: 13.00 mm to 15.5 mm
- o Basic Curve: 8.00 mm to 9.50 mm
- o Center Thickness: 0.08 mm to 0.14 mm (dependent on power)
- o Powers: -0.50D to -7.00D in 0.25 steps

The optic zone design is a concentric ring design with alternating vision correction zones and treatment zones (shaded in diagram). Zones 1 and 3 are vision correction zones and the label power of the contact lens. Zones 2 and 4 are treatment zones with 2 diopters of defocus to slow the progression of myopia.



The physical/optical properties of the lens are:

- o Refractive Index: 1.395 ± 0.005
- o Light Transmittance: > 90%
- o Water Content: 60% + 2%
- o Oxygen Permeability: 25 x10⁻¹¹ (cm²/sec)(ml O₂/ml x mmHg) (Polarographic FATT Method)

ACTIONS

When placed on the cornea in its hydrated state, the **MiSight** daily wear single use (omafilcon A) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina and to simultaneously provide an optical stimulus to slow the progression of myopia.

INDICATIONS FOR USE

MiSight® 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 to -4.00 diopters (spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.

CONTRAINDICATIONS

Do not use the **MiSight** daily wear single use lens when any of the following conditions exist:

- 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 handling and wear regimen or unable to obtain assistance to do so.

WARNINGS

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

- o **PROBLEMS WITH CONTACT LENSES COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lens. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. 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.
- o **WATER ACTIVITY**
 - Do not expose the contact lenses to water while wearing them.
 - Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submerged when swimming in pools, lakes, or oceans, discard them and replace them with a new pair.
 - Ask eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

o EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE FOLLOWING IS EXPERIENCED:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes;
- Loss of Vision,
- Eye Redness
- Or Other Eye Problems

PATIENTS SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PRACTITIONER.

- o 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 risk of serious adverse reactions is increased when these lenses are worn overnight.
 - o Single Use, Daily Disposable lenses are not intended for cleaning or re-use, and on removal should be discarded and a fresh pair used each day.
 - o Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
 - o MiSight lenses provide an optical correction that simultaneously presents one image "in-focus" and a second image "out-of-focus." Under certain circumstances (such as low light levels), this optical design can cause the following visual symptoms for some patients:
 - o Reduced image contrast;
 - o A ghost image (double image, with a mild second image seen);
 - o Halos around bright lights; and glare around lights.
- Not all patients function equally well with this type of correction. This type of correction can create a vision compromise that may cause difficulties with certain visually-demanding tasks. Patients should exercise extra care if performing potentially hazardous activities.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- o 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.
- o 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.

- o 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.
- o 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.
- o 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 safety precautions:

- o Lenses prescribed on a daily wear single use wearing schedule should always be discarded when removed at the end of the wearing day.
- o The compatibility of the lens with lens care regimens has not been evaluated.
- o Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- o 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.
- o 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.
- o 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.
- o Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for **MiSight** contact lenses and those prescribed by the eye care practitioner.
- o Never wear lenses beyond the period recommended by the eye care practitioner.
- o If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- o Always handle lenses gently and avoid dropping them.
- o Avoid all harmful or irritating vapors and fumes while wearing lenses.

- o Ask the eye care practitioner about wearing the lenses during sporting activities.
- o Inform the doctor (health care practitioner) about being a contact lens wearer.
- o 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.
- o Do not touch the lens with fingernails.
- o Always contact the eye care practitioner before using any medicine in the eyes.
- o 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.
- o 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.
- o Although the clinical study demonstrated decreased progression in myopia during its three-year duration with the **MiSight** lenses, any potential benefits beyond the three-year study, specifically with regard to the further slowing

of myopic progression or the prevention of future retinal disease have not been determined.

- o Several inclusion/exclusion criteria restricted participating subjects in the **MiSight** pivotal study to those in whom contact lens wear might pose greater risks, and to those with characteristics that might reduce the effectiveness of the treatment. Thus, the safety and effectiveness of the use of the device in these types of patients is not known. Patients with the following characteristics were not studied:
 - o Best corrected visual/acuity worse than 20/25;
 - o Younger than 8 or older than age 12 at initiation of treatment (no patient was seen in any year of the study who was older than age 15);
 - o Spherical equivalent refractive error lower than -0.75 D or higher than -4.00 D at initiation of treatment
 - o Astigmatism > 0.75 D at initiation of treatment
 - o Anisometropia ≥ 1.00 D at initiation of treatment
 - o Exhibiting poor personal hygiene;
 - o Born earlier than 30 weeks or weighed less than 1500g (3.3lb) at birth;
 - o Regularly using of ocular medications (prescription or over-the-counter), artificial tears, or wetting agents;
 - o Currently using systemic medications which may significantly affect contact lens wear, tear film production, pupil size, accommodation or refractive state. Such as, but not limited to: long term use of nasal decongestants (for example, pseudoephedrine, phenylephrine), antihistamines (for example, chlorpheniramine, diphenhydramine), prednisolone or Ritalin (methylphenidate).
 - o With a history of corneal hypoesthesia (reduced corneal sensitivity), corneal ulcer, corneal infiltrates, ocular viral or fungal infections or other recurrent ocular infections.
 - o Showing strabismus by cover test;
 - o Having known ocular or systemic disease such as, but not limited to: anterior uveitis or iritis, episcleritis or scleritis, glaucoma, Sjögren's syndrome, lupus erythematosus, scleroderma, or diabetes;
 - o Having known ocular or systemic or neuro-developmental conditions that could influence refractive development. Such as, but not limited to: persistent pupillary membrane, vitreous hemorrhage, cataract, corneal scarring, ptosis eyelid hemangiomas, Marfan's syndrome, Down's syndrome, Ehler's-Danlos syndrome, Stickler's syndrome, ocular albinism, retinopathy of prematurity;
 - o Having keratoconus or an irregular cornea;
 - o Showing biomicroscope findings that would contraindicate contact lens wear including, but not limited to: neovascularization; active anterior segment ocular disease, grade 3 or 4 abnormalities

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- o Eyes stinging, burning, or itching (irritation), or other eye pain.
- o Comfort is less than when the lens was first placed on the eye.
- o Feeling that something is in the eye such as a foreign body or a 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 Sensitivity to light (photophobia).
- o Dry eyes.

When any of the above problems occur, it may be a symptom of a serious condition such as corneal infection, corneal ulcer/opacity, infiltrative keratitis, corneal abrasion, corneal edema, neovascularization, or iritis. Some of these adverse events can

