

MiSight 1 Day (omafilcon A)

SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR

PROFESSIONAL FITTING AND INFORMATION GUIDE



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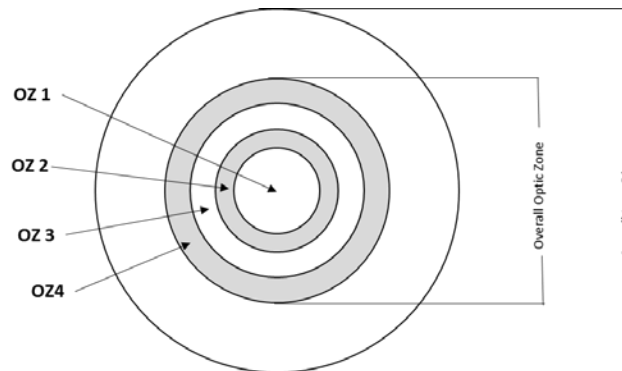
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PRODUCT DESCRIPTION

MiSight 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear 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.

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: $60\% \pm 2\%$
- o Oxygen Permeability: $25 \times 10^{-11} \text{ (cm}^2\text{/sec)(ml O}_2\text{/ml x mmHg)}$ (Polarographic FATT Method)

LENS PARAMETERS AVAILABLE

Diameter	14.2 mm
Base Curve	8.7 mm
Center Thickness	0.08 mm to 0.14 mm (varies with power)
Sphere Power	-0.50 D to -7.00 D; 0.25D steps

See Price List for Detailed Availability

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, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please refer to the Package Insert (PI01082).

SELECTION OF PATIENTS

- The MiSight Soft Contact Lenses can be prescribed to patients who require vision correction and desire to slow the progression of myopia.
- Parental consent and cooperation when fitting young children is important. Patients selected to wear MiSight Soft Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. Patient hygiene and ability to follow practitioner instructions are essential to success.

FITTING PROCEDURE

PRE-FITTING EXAMINATION

- An examination, including personal and family history, refraction, keratometry, biomicroscopy, and other pertinent tests and measurements should be performed to rule out contraindications to contact lens wear as described in the Package Insert. If the patient has the necessary qualifications and no contraindications exist, the patient may be considered for fitting.

INITIAL LENS SELECTION

- MiSight (omafilcon A) contact lenses are available in a single base curve and diameter. The soft lens polymer and thin lens design allow for draping across a broad range of corneal curvatures.
- Initial lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. A cycloplegic refraction can be a helpful baseline reference before an initial fitting of MiSight lenses. Because of the dual focus optical design of MiSight lenses, it is best to start with maximum plus/least minus lens power that provides good visual acuity.
- Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- The lens should cover the patient's cornea fully, provide discernible movement (0.2 mm to 0.5 mm is ideal) after blink, be comfortable for the patient and provide satisfactory visual performance.
- Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.

INITIAL LENS EVALUATION

- Comfort - If the patient experiences lens awareness or discomfort, check to make sure there is no foreign matter under the lens, or the lens is not inside-out or damaged.



- Lens Centration and Movement - Excessive decentration or lens movement may result in unstable vision and is often a sign that the lens is loose. A 0.2mm to 0.5mm range of movement is ideal. See LENS FIT GUIDELINES below.
- Visual Acuity and Power Adjustment - Visual acuity of 20/20 should be achievable for spherical corrections or with low amounts of astigmatism. To avoid over-minusing, reduce minus in 0.25D steps provided there is no decrease in acuity and no subjective visual impact. Increase minus in 0.25D steps only if it significantly improves distance vision.
- Vision Quality - 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 reduced image contrast, symptoms of ghost images, and/or glare or halos around bright lights. See the related Warning concerning these problems in the Package Insert. Final Lens Selection - Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.

LENS FIT GUIDELINES

Characteristics of a Well-fitted Lens

A well-fit MiSight Contact Lens best satisfies the following criteria:

- Full corneal coverage in all directions of gaze.
- Good centration (concentric about the visible iris).
- Satisfactory lens movement (0.20 to 0.50 mm with blink is ideal)
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

CHARACTERISTICS OF A TIGHT-FITTING LENS

A tight-fitting MiSight Contact Lens would display some or all of the following characteristics:

- Good centration.
- Little or no movement with blink or up gaze lag.
- The lens resists movement when manipulated with digital pressure against the lower lid.
- Good comfort
- Vision may be blurred and clear immediately following blink.
- Bubble(s) under the lens.
- Conjunctival indentation and/or blanching of limbal vessels at the lens edge.
- Limbal-conjunctival hyperemia.

CHARACTERISTICS OF A LOOSE-FITTING LENS

A loose-fitting MiSight Contact Lens would display some or all of the following characteristics:

- Decentration (usually temporally and/or superiorly).
- Excessive up gaze lag (>1.0mm).



- Reduced comfort response-usually lower lid sensation.
- Unstable vision.

PATIENT INSTRUCTION

- When fitting contact lenses to children, it is important that the child is able to insert and remove lenses by themselves but that the parents are aware and knowledgeable as well. Discuss with the parents the best approach for their child.
- Instruct the patient on the technique for soft lens insertion and removal. Insertion and removal is done in the conventional manner used for soft hydrophilic contact lenses. Provide written instructions and a copy of the MiSight (omafilcon A) Contact Lens Patient Instruction Booklet. It is advisable to review these instructions carefully with your patient but also with their parent(s) .
- It is normal for the new wearers to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight eye redness during the adaptation period. Although the adaptation period varies for each individual, generally within a few days these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

RECOMMENDED WEARING SCHEDULE

- New contact lens wearers may wish to increase their wearing time slowly over the first week as they adapt to handling and wearing lenses. A suggested maximum wearing time for the first week may be as follows:

DAY	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
HOURS	6	8	10	12	14	All waking hours

- Based on the clinical study, it is recommended that the patient wear the lens for a minimum of 10 hours per day for at least 6 days per week. Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping.
- The MiSight lenses are indicated for daily disposable replacement. The lenses should be thrown out at the end of each day.

FOLLOW-UP CARE

- It is recommended during the first several months of wear, that children wearing contact lenses see their eye-care practitioner more often to assure good contact lens hygiene practices are developed.
- Thereafter, it is recommended that a contact lens-wearing patient see his or her eye-care practitioner at least twice each year.
- Follow-up Care for contact lens wear should include at least the following:
 - o Case history/ symptoms
 - o Visual acuity and over-refraction. Avoid over-minusing as described above.
 - o Check lens fit (see LENS FIT GUIDELINES)



- o Biomicroscopic examination (with and without the use of fluorescein) of the cornea, conjunctiva and lids.

If any of the above observations are judged to be abnormal, professional judgment is to be used in alleviating the problem and restoring the eye to optimal conditions.

- Prescribe new lens power if necessary.

CARE OF LENSES

MiSight (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

Please refer to the Package Insert and the Patient Information Booklet for more information.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing sterile isotonic buffered saline solution. The blisters are packed in boxes. The following information is provided: the base curve, diameter, dioptric power, manufacturing lot number of the lens and the expiration date of the product.

REPORTING ADVERSE ACTIONS

All serious adverse experiences and adverse reactions in patients wearing the MiSight 1 DAY (*omafilcon A*) Soft (Hydrophilic) Contact Lens or experienced with the lenses should be reported to:

CooperVision, Inc.

Attn: Product Services

711 North Road

Scottsville, New York 14546

(800) 341-2020

www.coopervision.com

