

2-Weeks
Aspheric
Contact Lens










**PROFESSIONAL FITTING
& INFORMATION GUIDE**

aveo

SOFT CONTACT LENS

SYMBOLS KEY

The following symbols may appear on the label or carton:

Symbol	Definition
	Caution, consult accompanying documents
	Do not use if package is damaged
	Material is recyclable
	Sterilized using steam or dry heat
	By prescription only
	Quality system certification symbol and notified body number
BC	Base curve
DIA	Diameter
PWR	Power
	Batch code
	Use by date
	Authorized Representative in the European Community

DESCRIPTION

aveo™ 2-Weeks Aspheric Soft Contact Lens (Omafilcon A) with UV Block contains 55% water and 45% Omafilcon A when hydrated. These lenses are stored in buffered saline and are intended to be used as daily wear contact lenses for up to TWO (2) weeks.

In its hydrated state, the contact lens acts as a refracting medium to focus light rays on the retina, when placed on the cornea. The lenses are tinted in light blue to assist handling. The lens polymer contains UV absorber to block UV radiation.

LENS PARAMETERS

Powers: -0.50D to -6.00D (in 0.25D increments)
-6.50D to -10.00D (in 0.50D increments)
+0.50D to +4.00D (in 0.25D increments)
+4.50D to +6.00D (in 0.50D increments)

Base Curve: 8.60 mm

Diameter: 14.20 mm

Centre Thickness: 0.070 mm at -3.00D (varies with power)

LENS PROPERTIES

Specific Gravity: 1.128 g/cm³

Refractive Index (Hydrated): 1.4009

Water Content: 50%

Oxygen Permeability: 17.87 (cm²/sec) (ml O₂/ml x mm Hg)

Surface Character: Hydrophilic

Tint: Light blue

ACTIONS

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

WEARING INDICATIONS (USES)

The aveo™ 2-Weeks Aspheric Soft Contact Lenses with UV Block are indicated for the optical correction of refractive ametropia in phakic persons with non-diseased eyes that are myopic or hypermetropic and exhibit astigmatism up to approximately 1.00D.

The lenses are intended for daily wear for up to TWO (2) weeks only. The UV blocker in the lens provides protection against transmission of harmful UV radiation to the cornea and into the eye.

WARNING: UV blocking contact lenses are not substitutes for protective UV absorbing eyewear such as sunglasses as they do not completely cover the eye and surrounding areas. Advise your patients on using UV absorbing eye wear as appropriate.

CONTRAINDICATIONS (Reasons Not to Use)

These lenses should not be worn if any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Inadequate tear film (severe dry eye)
- Reduction in corneal sensation (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- The use of medications, including eye medications
- If eyes become red or irritated
- Periods of poor health, such as severe colds or influenza

WARNINGS

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

Problems with contact lenses or lens care products could result in serious eye injury. If the patient experiences one or more of the following signs:

- Eye discomfort / pain
- Excessive tearing
- Sensitivity to light
- Eye redness
- Reduced sharpness in vision / vision loss
- Severe or persistent dry eyes
- Uncomfortable lens
- Other eye problems

Instruct the patient to remove the lens immediately. Promptly seek the assistance of an Eye Care Professional if the above symptoms continue after removal or upon reinsertion of the lens. A serious condition such as corneal ulcer (ulcerative keratitis), infection, or iritis may be present. These conditions could progress rapidly and may lead to permanent vision loss.

Lenses that are prescribed for daily wear needs to be removed while sleeping. The risk of serious adverse reactions is increased when lenses are worn overnight.

If a lens sticks (stop moving), instruct the patient to apply several drops of lubricating solution / rewetting drops to the eye and wait till the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the Eye Care Professional.

Smoking increases the risk of ulcerative keratitis for contact lens users, especially when worn overnight.

The overall risk of corneal ulcer may be reduced by adhering to proper lens care procedure.

Special Instructions for Use & Warnings:

• Water Activity

Do not expose contact lenses to water while wearing them.

WARNING: *Water can harbour microorganisms that can lead to severe infection, vision loss, or blindness. The patient should be instructed to discard the lenses and replace with a new pair if the lenses have been submersed in water when participating in water sports or swimming in pools, lakes, oceans or hot tubs. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any water activity.*

• Soaking and Storing Your Lenses

Discard solution from lens case after each use. Use only fresh multipurpose solution for soaking the lenses.

WARNING: *Re-using or topping-up old solution reduces effective lens disinfection and could cause severe eye infection, vision loss or blindness.*

• Discard Date on Multipurpose Solution Bottle

Discard any remaining solution after the recommended time period indicated on the multipurpose solution bottle.

The Discard Date refers to the time that the patient can safely use contact lens care product after the bottle has been opened, whereas Expiration Date refers to the last date the product is still effective before it is opened.

WARNING: *Using multipurpose solution beyond the discard date could result in severe eye infection, vision loss or blindness. To avoid contamination, make sure the tip of the bottle does not contact any surface. Replace cap after using. To avoid contaminating the solution, DO NOT transfer the solution to other bottles or containers.*

• Rub and Rinse Procedure

Rub and rinse the lenses according to the recommended lens rubbing and rinsing times stated in the multipurpose solution's label.

WARNING: *Rubbing and rinsing lenses according to the recommended amount of time help prevent serious eye infections. Never use water, saline solution or rewetting drops to disinfect the lenses. Not using the recommended disinfectant can lead to severe eye infection, vision loss or blindness.*

• Lens Case Care

Empty and clean contact lens case with digital rubbing, followed by rinsing using fresh sterile multipurpose solution and allow to air dry. Avoid using water altogether.

Replace the lens case according to the instructions given by the Eye Care Professional or the manufacturer's instructions.

Contact lens cases can be a source of bacterial growth.

WARNING: *Always use fresh sterile multipurpose solution to prevent contamination to the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.*

PRECAUTIONS

Eye Care Professional should exercise the following special precautions when handling contact lenses:

- As only a small number of patients were enrolled in the 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 Professional should consider the 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 Professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses will absorb the dye and become discoloured. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Patients who wear these lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses from him / her.
- Instruct the patient to remove the lenses immediately if eyes become red and/or irritated.
- As with any contact lens, follow-up visits are essential to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Handling Precautions:

- DO NOT use if the sterile blister package is opened or damaged.
- Always wash hands thoroughly in warm soapy water before handling the lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. Water-based cosmetics are less likely to damage lenses than oil-based products.
- DO NOT touch contact lenses with the fingers or hands if the hands are not free of foreign materials. Microscopic scratches that may occur, may cause distorted vision and/or injury to the eye.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when daily disposable lenses are worn. The lenses should be disposed of upon removal and have spare lenses or spectacles as backup.

Lens Wearing Precautions:

- Only wear the lenses within the period recommended by the Eye Care Professional.
- Exercise caution and keep eyes closed when using aerosol products such as hair spray when wearing lenses until the spray has settled.
- The patient should be advised to never allow anyone else to wear their lenses. Sharing lenses greatly increases the chance of eye infections.

Other Topics to Discuss with Patients:

- Always inform the Eye Care Practitioner/Health Care Professional before using any medicine in the eyes.
- Patient should always inform their employer of being a contact lens wearer. Some jobs may require the patient not wear contact lenses.
- Certain medications, such as antihistamines, decongestants, diuretics, tranquilizers, muscle relaxants may cause symptoms such as dry eyes, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed.

GENERAL FITTING GUIDELINES

1. Patient Selection

The Eye Care Professional should determine if the patient is a good contact lens candidate based on the following:

- Motivation to wear contact lenses
- General health
- Ability to follow instructions on proper lens care and handling procedure
- Ability to understand the risk and benefits of lens wear

Patient who do not meet the above criteria should not be considered for contact lenses.

2. Pre-fitting Examination

The pre-fitting examination should cover the following:

- Thorough case history to determine possible contraindications for lens wear.
- Acuity measurement
- A spherocylindrical refraction
- Slit lamp examination
- Tear film assessment
- Keratometry

3. Initial Power Determination

Place a lens on the eye once the contact lens power has been determined. Compensate for vertex distance if the refraction is greater than $\pm 4.00D$.

4. Trial Lens Fitting

Allow the lens to settle on the eye for approximately 10 minutes. Assess patient comfort, the fitting of the contact lens on the eye and final power verification.

i. Characteristics of an Optimal Fit

The lens should display good centration, full corneal coverage, move freely on push-up test and return to its properly centred position when released.

The lens should be comfortable and provides stable acuity. There should be sufficient movement to provide tear exchange under the contact lens after each blink.

ii. Characteristics of a Steep (Tight) Fitting Lens

The lens will be difficult to move or not move at all on push-up test and acuity will demonstrate poor end point.

A lens that is judged to be steep fitting shouldn't be dispensed to the patient. A flatter lens (larger base curve), if available, should be trial fit and evaluated.

iii. Characteristics of a Flat (Loose) Fitting Lens

The lens will move an excessive amount on push up test and acuity will be variable. There may be excessive lens movement during blink in primary or upward gaze.

A lens that is judged to be too flat shouldn't be dispensed to the patient. A steeper lens (smaller base curve), if available, should be trial fit and evaluated.

5. Final Lens Power

Perform an over-refraction to determine the final lens power. Complete over-refraction using best vision spheres first.

Example: Diagnostic lens	-3.00 D
Spherical over-refraction	-0.25 D
Final lens power	-3.25 D

The patient should be able to achieve good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Perform a full refraction with cylinder lenses if the acuity remains poorer than with spectacles.

If vision is acceptable, dispense the lenses and instruct patient to return for follow up in 1 week's time.

All patients should be supplied with a copy of the **PATIENT INSTRUCTION GUIDE** for these lenses. Copies are available for download at www.aveovision.com.

MONOVISION FITTING GUIDELINES

1. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near acuity in each eye. Patients with reduced visual acuity, such as amblyopia may not be a good candidate for monovision correction.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for activities such as:

- i. Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- ii Driving automobiles (e.g. driving at night). Patients who cannot meet their driver's license requirements with monovision correction should not drive with this correction. Additional over-correction may be required to improve vision.

Patient Education

Not all patients function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they would have with spectacles (e.g. reading, bifocal, trifocal or progressives). Each patient must understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks.

During the fitting process, the patient must realize the disadvantages and the advantages of clear near vision, straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following methods to test for eye dominance can be used:

a. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting eye". Get the patient to point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant eye.

Method 2: Determine which eye will accept the added power with the least reduction in distance vision. Place a trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with near ADD lens over the right or left eye.

b. Refractive Error Method

For anisometric correction, it is generally best to fit the more hypermetropic eye for distance and more myopic eye for near.

c. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If the patient's gaze for near tasks is usually for one direction, correct the eye on that side for near.

Example:

A person who places copy to the right side of the desk will function best with the near lens on the right eye.

3. Special Fitting Considerations

a. Unilateral Lens Correction

There are circumstances where only one contact lens is required. For example an emmetropic patient would only need a near lens, while a bilateral myope would require only a distance lens.

Examples:

- **Emmetrope:** A presbyope emmetropic patient who requires a +1.50D ADD would have a +1.50 lens on the near eye and the other eye would be without a lens.
- **Bilateral Myope:** A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and left eye uncorrected for near.

b. Near ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

c. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the **GENERAL FITTING GUIDELINES** for base curve selection described in this guide.

Case history and standard clinical evaluation procedures should be used to determine the prognosis. Determine the distance correction and the near correction. Next, determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Let the lens settle for approximately 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavourable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

d. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some dizziness, headaches, mild blurred vision and feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persists, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it is recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive under optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

e. Other Suggestions

The success of monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical viewing distance is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet their driver's licensing requirements with a monovision correction.

- Use of proper illumination when carrying out visual tasks.

The following suggestions may improve the success in fitting monovision:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens power if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with monovision correction is most appropriately left to the Eye Care Professional in conjunction with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the **PATIENT INSTRUCTION GUIDE**, which contains important information for monovision wearer. Copies are available for download at www.aveovision.com.

PATIENT MANAGEMENT

Dispensing Visit

Supply the patient with a copy of the Patient Instruction Guide for these lenses. Review these instructions with the patient so that he/she clearly understands the prescribed wearing and replacement schedule (disposable or frequent replacement).

Recommend an appropriate cleaning and disinfecting system and provide the patient with proper lens care instructions. Chemical or hydrogen peroxide is recommended.

Schedule a follow-up examination.

Follow-up Examinations

To ensure continued successful contact lens wear, follow-up care should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, daily disposable modality and proper lens handling procedures.

1. Recommended **Follow-Up Examination Schedule** (complications and specific problems should be managed on an individual patient basis):
 - i. One week from the initial lens dispensing to the patient
 - ii. One month post-dispensing
 - iii. Every 3 – 6 months thereafter

NB: Lens should be preferably worn for at least 6 continuous hours prior to the follow-up visit.
2. Recommended **Procedures for Follow-Up Visits:**
 - i. Record patient's symptoms, if any.
 - ii. Measure visual acuity monocularly and binocularly with the contact lenses in place.
 - iii. Perform an over-refraction to check for residual refractive error.
 - iv. With a biomicroscope, evaluate lens fitting characteristics (as described in the **GENERAL FITTING GUIDELINES**) and examine the lens surface for deposits and damage.

- v. Remove the lenses and examine the cornea and conjunctiva with biomicroscope and fluorescein (unless contraindicated).
- vi. Evert upper lids to determine condition of tarsal conjunctival.
- vii. Observations:
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal oedema.
 - The presence of corneal staining and/or limbal-conjunctiva hyperaemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - Changes in the papillary conjunctiva may be indicative of an unclean and/or damaged lens.
- viii. Record Keratometry readings and perform spectacle refractions periodically. The values should be recorded and compared to the baseline measurements.

When observations are abnormal, use professional judgement to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and re-fit the patient.

WEARING SCHEDULE

The wearing and replacement schedule as well as aftercare check-ups should be determined by the Eye Care Professional. The patient must remove the lenses while sleeping.

As there is a tendency for patients to over wear their lenses initially, the Eye Care Professional should emphasise on the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based on the patient's physiological eye condition, as each wearer's response to contact lenses varies.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	4–6
2	6–8
3	8–10
4	10–12
5 and after	12–14

REPLACEMENT SCHEDULE

aveo™ 2-Weeks Aspheric Soft Contact Lenses with UV Block are prescribed for daily wear. It is recommended that the lenses be replaced with a new lens every 1 month or as advised by the Eye Care Professional.

The Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon the patient's response.

The patient's replacement schedule can be determined based upon the patient's history and their ocular health, as well as the Eye Care Professional's clinical judgement.

LENS CARE DIRECTIONS

The Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for lenses prescribed in accordance with the patient's lens type and wearing schedule. The Eye Care Professional should recommend an appropriate care system according to the patient's needs.

Further information relating to contact lens care and handling can be found in the Patient Instruction Guide. Copies are available for download at www.aveovision.com.

The Eye Care Professional should review with the patient proper lens care regime for cleaning, disinfecting and storing, as well as basic lens care information and specific instructions.

Basic Instructions

- i. Before handling contact lenses, always wash, rinse and dry hands thoroughly.
- ii. Only use recommended solutions for lubricating or rewetting lenses.
- iii. Store lenses at room temperature (15°C – 25°C / 60°F – 80°F).

Care for a Dried Out (Dehydrated) Lens

If the frequent replacement lens is off the eye and exposed to air between 30 minutes to 1 hour or more, its surface will become dry and gradually become non-wetting. If this occurs, discard the lens and use a new one.

Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving), instruct the patient to apply several drops of recommended lubricating/rewetting solution to the eye and wait until the lens begins to move freely on the eye before removing it.

If the lens continues to stick, the patient should **IMMEDIATELY** consult the Eye Care Professional.

ADVERSE REACTIONS

The following problems may occur during contact lens wear:

- Foreign body sensation
- Burning, stinging, itching or watery eyes
- Eye redness
- Sensitivity to light
- Rainbows or halos around lights
- Discomfort / Pain
- Reduced sharpness in vision / vision loss
- There may be potential for some temporary impairment due to corneal erosion, peripheral corneal ulcers, or peripheral infiltrates. There may be potential for other physiological observations, such as local or generalized oedema, corneal neovascularization, tarsal abnormalities, corneal staining, injection, iritis and conjunctivitis; some of which are clinically acceptable in low amounts.

If any of the above signs or symptoms occurs, do not ignore it as it may lead to more serious complications. The eye care professional should instruct the patient to do the following:

- Remove the lens IMMEDIATELY
- If the discomfort or problem stops, inspect the condition of the lens
- If the lens is damaged in any way, DO NOT reinsert the lens back on the eye. Replace with a new lens.
- If the lens have dirt, an eyelash or a foreign body on it, clean, rinse and disinfect the lens before reinsertion.
- If the symptoms persists after lens removal, seek the assistance of the Eye Care Professional.

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 eye IMMEDIATELY with tap water and contact the Eye Care Professional or visit the hospital eye service without delay.

ADVERSE REACTIONS REPORTING

Report all serious adverse reactions observed in patients to:

Supermax Vision UK Limited

Peterborough Cambridgeshire
PE1 5DD
United Kingdom.

Supermax Healthcare Inc.

1899 Sequoia Dr, Aurora, IL60506
United States.
US Toll Free Telephone No.: 1-877-287-3542

HOW SUPPLIED

The contact lens is supplied in sterile state and packed in the blister package which made from medical grade polypropylene blister and aluminium/polypropylene laminated foil lid. Information such as 2D barcode, power, lens base curve, diameter, lot Number and expiry date are printed on the foil. The contact lens is immersed in phosphate buffered packaging saline.