

aveoTM BRAND CONTACT LENSES

aveoTM 1-Day Aspheric Soft Contact Lens

aveoTM 1-Day Toric Soft Contact Lens

PATIENT INSTRUCTION GUIDE

Soft Hydrophilic Contact Lenses
with UV Blocker for Daily Wear

PATIENT INSTRUCTION GUIDE

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This booklet contains important information on how to safely use contact lenses for the following brands:

- **aveo™ (Filcon II 2) 1-Day Aspheric Soft Contact Lens**
 - **aveo™ (Filcon II 2) 1-Day Toric Soft Contact Lens**
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- Contact lenses are medical devices. Contact lens fittings should always be done by your Eye Care Professional.
 - It is important that you wear your contact lenses only as prescribed by your Eye Care Professional.
 - Keep this booklet. You may need to read it again.
 - If you have any further questions, ask your Eye Care Professional.
 - Discuss with your Eye Care Professional on the frequency of your contact lens aftercare.

INTRODUCTION

aveo™ 1-Day Soft Contact Lenses with UV Block are single use soft hydrophilic (“water loving”) contact lenses.

Daily disposable lenses are to be worn once (single use only) during waking hours and should be discarded upon removal. Therefore, no care system is required.

The lenses are tinted in light blue to assist handling. It also contains ultraviolet (UV) absorbing ingredient to block UV radiation from entering the eye.

Your Eye Care Professional will review with you the instructions for proper lens care and handling. To ensure successful lens wear and performance, you must carefully follow instructions, adhere to wearing schedule and attend regular aftercare appointment.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION	REFERENCES
	Caution	ISO 15223-1 Table 1 Symbol 5.4.4
	Consult instructions for use	ISO 15223-1 Table 1 Symbol 5.4.3
	Manufacturer	ISO 15223-1 Table 1 Symbol 5.1.1
	Date of manufacture	ISO 15223-1 Table 1 Symbol 5.1.3
	Do not use if package is damaged and consult instructions for use	ISO 15223-1 Table 1 Symbol 5.2.8
	Material is recyclable	-
	Do not re-use	ISO 15223-1 Table 1 Symbol 5.4.2
	Sterilized using steam	ISO 15223-1 Table 1 Symbol 5.2.5
	Single sterile barrier system	ISO 15223-1 Table 1 Symbol 5.2.11
	By prescription only	-
	Conformity mark indicating compliance with applicable European Union legislation	-
BC	Base curve	-
DIA	Diameter	-
PWR	Power	-
CYL	Cylinder power	-
AXIS	Cylinder axis	-
R	Right	-
L	Left	-
	Batch code	ISO 15223-1 Table 1 Symbol 5.1.5
	Use by date	ISO 15223-1 Table 1 Symbol 5.1.4
	Authorised representative in the European Union	ISO 15223-1 Table 1 Symbol 5.1.2
	Medical Device	ISO 15223-1 Table 1 Symbol 5.7.7

SYMBOL	DEFINITION	REFERENCES
	Do not re-sterilize	ISO 15223-1 Table 1 Symbol 5.2.6
	Importer, to indicate the entity importing the medical device into the locale	ISO 15223-1 Table 1 Symbol 5.1.8
	Unique Device Identifier	ISO 15223-1 Table 1 Symbol 5.7.10

GLOSSARY

The following medical / technical terms may appear regularly in this booklet.

Aftercare	Follow-up appointments after your contact lenses have been fitted
Ametropia	Abnormal vision requiring correction for proper focus
Aspheric contact lens	A lens with a curve that is not round, but has different shapes across its surface
Astigmatism	A common vision condition in which the cornea is irregularly shaped, resulting in distorted or blurred vision
Cornea	Clear front part of the eye
Inflammation	Swelling, redness and pain
Myopia	Short sightedness
Hypermetropia	Long sightedness
Phakic	An eye with natural crystalline lens
Presbyopia	A condition in which the natural crystalline lens in the eye loses some of their elasticity. Its oval shape cause the visual image to be out of focus (blurred)
Ulcerative keratitis	Also known as corneal ulcer. It is an open sore on the cornea. This condition can cause permanent vision loss if left untreated.

WEARING RESTRICTIONS & INTENDED PURPOSE

This device is a corneal contact lens intended for the optical correction of refractive ametropia in phakic persons with non-diseased eyes.

aveo™ Aspheric Soft Contact Lens is indicated for the optical correction of refractive ametropia in phakic persons with non-diseased eyes that are myopic or hypermetropic.

aveo™ Toric Soft Contact Lens is indicated for the optical correction of refractive ametropia in phakic persons with non-diseased eyes that are myopic and may have astigmatism between 0.50D to 2.50D.

These 1-Day Lenses are daily disposable contact lenses intended for single-use during waking hours only, and should be discarded upon removal.

The soft contact lenses provide protection against transmission of harmful UV radiation to the cornea and into the eye.

WARNING: UV-absorbing contact lenses do not serve as substitutes for protective UV-absorbing eyewear as they do not entirely cover the eye and surrounding areas. The patient should continue to use their UV-absorbing eyewear as recommended.

NOTE: Exposure to UV radiation over a long period of time may result in cataracts. The exposure may be from personal factors such as the extent and nature of outdoor activities; and environmental conditions such as altitude, cloud cover and geography. UV-blocking contact lenses shield against harmful radiation. However, clinical studies have not been undertaken to demonstrate that contact lenses with UV-blocking properties reduces risk of cataract development or other ocular disorders. The patient should consult his/her Eye Care Professional for more information.

The **aveo™ Soft Contact Lenses** described in this booklet should be removed from your eyes at the end of the day (i.e. lenses should be removed every night before sleeping) and discarded upon removal. DO NOT wear your contact lenses while sleeping.

INTENDED PATIENT POPULATION

The device is intended for patients with refractive ametropia (myopia, hyperopia, and where applicable, astigmatism) who have healthy, non-diseased eyes and for whom contact lens wear is clinically appropriate, as determined by an Eye Care Professional.

The device is intended for individuals aged 16 years and above.

No device-specific contraindications related to pregnancy or breastfeeding have been identified. As physiological changes (e.g., hormonal variations) may influence tear film stability and contact lens tolerance, suitability for lens wear in pregnant or breastfeeding individuals should be determined on an individual basis by an Eye Care Professional.

INTENDED USER

This device is intended to be used by contact lens wearers (lay users) for the correction of refractive ametropia (myopia, hyperopia, and astigmatism).

The device is intended for individuals who are suitable for contact lens wear, as determined by an Eye Care Professional.

USER QUALIFICATION / TRAINING REQUIREMENTS

Contact lenses must be fitted and prescribed by a qualified Eye Care Professional.

The contact lens wearers must receive appropriate instruction and training from an Eye Care Professional on proper lens handling, insertion, removal, cleaning, disinfection, storage, and hygiene procedures prior to use.

CLINICAL BENEFITS

The clinical benefit of the soft contact lenses manufactured by Supervision Optimax Sdn Bhd is vision correction of refractive ametropia in phakic persons with non-diseased eyes that are myopic or hypermetropic with or without astigmatism.

PRECAUTIONS

Always wash and rinse 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 based cosmetics are less likely to damage lenses than oil-based products.

If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Avoid all harmful or irritating vapours and fumes while wearing lenses.

DO NOT SLEEP in your contact lenses. When daily wear users wear their lenses overnight (outside the approved indication) the risk of corneal ulcer is greater.

DO NOT WEAR your lenses longer than recommended by your Eye Care Professional. Failure to do so may put you at significant risks of developing serious eye conditions.

Always consult your Eye Care Professional before using any medicine in your eyes.

Always inform your employer about being a contact lens wearer. Some jobs may require that you use eye protection equipment or not wear contact lenses.

Do not change your lens type (e.g. different brand) or parameters (e.g. lens power, base curve, diameter) without consulting your Eye Care Professional.

You should be able to insert and remove your lenses (or have someone else available who can remove the lenses for you) before leaving your Eye Care Professional's office.

All refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers due to the small number of patients enrolled in clinical investigation of the lenses. Thus, all lens characteristics that can affect the performance of the lens and ocular health, including oxygen permeability, optic zone diameter, central and peripheral thickness, should be taken into consideration by the Eye Care Professional when selecting appropriate lens design for initial dispensing and on-going monitoring.

CONTRAINDICATIONS (WHEN LENSES SHOULD NOT BE WORN)

Soft contact 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
- The presence of any eye disease, injury, or abnormality that may have an effect on the cornea, conjunctiva, or eyelids
- Any active corneal infection
- Inadequate tear film (severe dry eye)
- Reduction in corneal sensation (corneal hypoesthesia)
- Contact lens wear that may exaggerate any eye condition secondary to a systemic disease
- The use of medications, including eye medications
- If eyes become red or irritated
- Periods of poor health, such as severe colds or influenza
- Allergic reactions on the ocular surface induced or exaggerated by lens wear or preservatives in certain contact lens solutions.
- Allergic response to ingredients such as Thimerosal or mercury in contact lens solution.

WARNINGS

What you should know for successful contact lens wear:

Problems with contact lenses or lens care products could result in serious eye injury.

If you experience the following conditions:

- 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.

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.

You should remove your daily wear lenses while sleeping if not indicated for overnight wear. Clinical studies have found that the risk of serious adverse reactions is increased when lenses are worn overnight.

There is no cleaning or disinfection needed for lenses prescribed for single use daily disposable wear. Re-using lenses intended for single use may affect vision and cause infection, discomfort or irritation to the eye.

Smoking increases the risk of corneal ulcer for contact lens users, especially when worn overnight. The overall risk of corneal ulcer may be reduced by adhering to proper lens care procedure.

Specific Instructions for Use and Warnings:

- **Water Activity**

Instruction for Use

Contact lenses should not be exposed to water while being worn.

WARNING:

Water can harbour microorganisms that may lead to severe infection, vision loss, or blindness. If your lenses have been in contact with water when taking part in water sports or swimming pools, lakes or oceans, it is recommended that you discard them and use a brand new fresh pair of lenses. Consult your Eye Care Professional for recommendations about wearing your lenses during water activities.

LENS HANDLING, INSERTION & REMOVAL

It is important that you follow the lens handling, insertion and removal instructions in this booklet and those prescribed by your Eye Care Professional.

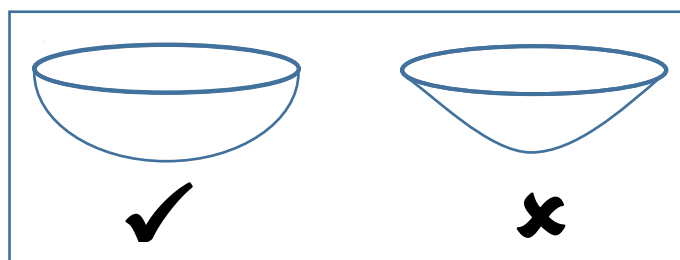
Step 1: Preparing for Your Lens Wear

1. Prior to handling your lenses, always wash your hands thoroughly with soap and dry them with a lint-free towel.
2. Avoid using oil-based soaps or lotion before handling your lenses as these may contaminate your lenses and disrupt lens comfort as well as clarity of vision.
3. Always put on your contact lenses first before applying any creams, makeups or hairspray.
4. Keep your fingernails clean and short to avoid tearing your contact lenses or scratching your eyes.
5. Your lens power (your contact lens prescription) may not be the same for each eye. Ensure that you wear the correct lens for each eye.
6. Check the “R” and “L” indicator on the carton box to identify if lenses are for use in the right or left eye.
7. Always check your blister pack to verify that the printed lens perimeters, e.g. power (D), base curve (BC), diameter (DIA) etc. match your contact lens prescription. Do not use if the information do not match.
8. To open individual lens package, always check to ensure your sterile blister package is not damaged in any way. Do not use if blister package is opened or damaged. Gently shake the blister pack before opening.
9. Peel back the foil and carefully remove the lens from the blister pack by carefully pouring it into the palm of your clean hand.

DO NOT use tweezers or other tools to remove your lenses from the blister pack as this could damage the lens.

Step 2: Spotting an Inside Out Lens

Before placing the lens on your eye, always check to ensure that the lens is not inside out. Follow the steps below:-



1. Remove the lens from the blister package.

2. Inspect the lens to make sure that it is clean, moist and free from nicks and tears. Discard and use a new lens if the lens appear damaged.
3. Place the lens on the tip of your dry finger.
4. Hold it in front of your eyes and look at the lens from the side.
5. If the lens is correctly positioned, it turns slightly in at the edges.
6. If the lens is inside out, its edge has a noticeable outward bend. Gently turn the lens the right way round before wearing it.
7. Wearing inside out lenses may cause discomfort and will move more on the eye.

Step 3: Putting On Your Contact Lenses

1. Place the lens (facing up like a bowl) at the tip of your index finger.
2. Always wear the contact lenses for your RIGHT eye first.
3. Check to make sure that the lens is not inside-out.
4. Use the middle finger of your right hand to pull down the lower eyelid and the index finger of your other hand to pull up your upper eyelid simultaneously.
5. Look up at the ceiling and place the lens onto the lower white part of your eye.
6. Remove your finger and look down into the contact lens. Blink gently several times to centre the lens.
7. Repeat the steps above for your other eye.

Step 4: Checking Your Lenses

1. Once the lenses are on your eyes, perform a self-assessment:
 - **Do the lenses feel good?**
 - **Do my eyes look good?**
 - **Is my vision good?**
2. If your vision is blurred, check if the lens is centred on the eye. See *Step 5: Lens Centration*.
3. If the lens is centred, remove the lens and check for the following possibilities:-
 - Traces of cosmetics or oil on the lens - Dispose the lens and insert a brand new fresh lens.
 - Inside out lens. See *Step 2: Spotting an Inside Out Lens*.
 - The lens is on the wrong eye.
4. If your vision remains blurred after checking the above possibilities, remove the lens and consult your Eye Care Professional.

Step 5: Lens Centration

1. The lens that is on the cornea will very rarely move onto the white part of the eye during wear.
2. However, this can occur if incorrect techniques are performed during lens insertion or removal.
3. To centre a lens, hold the upper and lower eyelids open with your fingers. While looking in a mirror, place a finger on the contact lens gently and slide the lens towards the centre of the eye.

Step 6: Removing Your Contact Lenses

CAUTION: Always check that the lens is centred on the cornea before attempting to remove the lens. Check your vision by covering the other eye. If vision is blurry, the lens may be off-centre or not in the eye at all.

1. Wash your hands with soap and dry them with a lint-free towel.
2. Always remove the contact lenses for your RIGHT eye first.
3. Look up at the ceiling and pull your lower eyelid down with the middle finger of your right hand.
4. Slide the lens down into the lower white part of your eye.
5. Squeeze the lens between your thumb and index finger and remove it carefully.
6. The lens should be discarded upon removal.
7. Repeat the steps above for your other eye.
8. Always remove your contacts lenses before you use your eye makeup remover.

There are other methods of lens insertion and removal. If you are experiencing difficulties with the above method, ask your Eye Care Professional to provide you with an alternative method.

CARING FOR YOUR LENSES

General Guidelines for Lens Care

- Prior to handling your lenses, always wash your hands thoroughly with soap and dry them with a lint-free towel.

- Never use non-sterile water, e.g. tap water, distilled water or homemade saline solution in the handling of your lenses. Exposure to these solutions increases the risk of serious microbial infection or injury.

OTHER IMPORTANT INFORMATION

Disposal of Contact Lenses

Dispose used contact lenses and foil lids in solid waste bins.

Dispose packaging in household recycling bins.

Torn Lens

In the event the lens tears in your eye, it will feel uncomfortable. Remove the pieces carefully by gently pinching them as you would do for a normal lens removal procedure. If the lens cannot be removed easily, rinse the eye thoroughly with sterile saline solution. Contact your Eye Care Professional for assistance if you still experience difficulty in removing parts of the lens. He / She can easily locate and remove the lens for you.

Sticking (Non-Moving Lens)

If a lens sticks (stop moving), apply several drops of lubricating solution / rewetting drops recommended by your Eye Care Professional 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, consult your Eye Care Professional immediately.

Sharing Lenses

Never allow anyone else to wear your lenses. The chance of eye infections increases when sharing lenses.

Wearing Schedule

The wearing schedule and maximum wearing time of your contact lenses should be determined by your Eye Care Professional as response to contact lenses varies according to individuals.

The recommended wearing time is 8 - 12 hours per day, as suggested in the mode of wearing time in 'MyHealth Portal' by Malaysian Ministry of Health's website

(<http://www.myhealth.gov.my/en/contact-lens-types-mode-of-wearing>). You must remove the lenses while sleeping.

CONTACT LENS AFTERCARE

Regular aftercare with your Eye Care Professional is important to determine the health of your eyes and how your eyes are responding to contact lenses. It is recommended that you visit your Eye Care Professional at least once a year, or more often if directed.

ADVERSE REACTIONS (POSSIBLE PROBLEMS WITH LENS WEAR)

The following problems may occur during contact lens wear:

- Foreign body sensation
- Burning, stinging, itching or watering eyes
- Eye redness
- Sensitivity to light
- Rainbows or halos around lights
- Discomfort / Pain
- Reduced sharpness in vision / vision loss

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. Dispose the affected lens and 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.

The following serious medical conditions may be associated with the above symptoms:

- Ocular irritation and/or corneal abrasion
- Toxic response
- Inflammatory response
- Blurred vision, reduced sharpness
- Ocular infection
- Corneal oedema (swelling)
- Corneal neovascularization
- Papillary conjunctivitis (inflammation of the eyelid)
- Eye redness
- Ocular discomfort / unsatisfactory performance
- Lens intolerance
- Contact lens related dry eye feeling
- Ulcerative keratitis (corneal ulcer)
- Permanent loss of vision in one or both eyes

Some of these conditions may progress rapidly and could result in permanent vision impairment if not promptly diagnosed and treated.

EMERGENCY

When your eye comes into contact with noxious vapour, chemicals or hazardous substances of any kind, e.g. household products, gardening solutions, laboratory chemicals, etc., you should:

1. Flush the affected eye IMMEDIATELY with tap water or sterile saline.
2. Remove the lens and store in appropriate storage solution and casing.
3. Contact your Eye Care Professional or visit a hospital emergency room without delay.

REPORTING OF ADVERSE REACTIONS

Any adverse reactions and serious incidents that has occurred in relation to this medical device should be reported to the manufacturer and your national authority:

Manufacturer: **Supervision Optimax Sdn Bhd**
Lot 38, Putra Industrial Park, Bukit Rahman Putra,
40160 Sungai Buloh, Selangor, Malaysia.

National Authorities Contact Points:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

HOW SUPPLIED

aveo™ Soft Contact Lenses are supplied sterile in a foil-sealed blister package. The packaging is marked with the base curve (BC), diameter (DIA), power (D), lot number, and use by date. Each sterile lens is packed immersed in a phosphate buffered saline solution and is steam sterilized.

YOUR WEARING SCHEDULE RECORD

Record your prescribed wearing schedule in the space below. It is important that you follow your Eye Care Professional's instructions regarding your contact lens wearing time. Do not sleep in lenses.

Day	Date	Wearing Time (as recommended by your Eye Care Professional)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		

Replacement Schedule:

Replace lenses every _____ days or every _____ weeks.

Your next aftercare date: _____

Notes:

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, CONTACT YOUR EYE CARE PROFESSIONAL IMMEDIATELY. DO NOT WAIT for your next appointment.



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