

**IMPORTANT:** Please read carefully and keep this information for future use.

This package insert is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

**clearday™ Beyond 1-day (Avefilcon A) DAILY DISPOSABLE  
SOFT SILICONE HYDROGEL CONTACT LENS  
(VISIBILITY TINT)**

clearday™ **Beyond 1-day**

**clearday™ Beyond 1-day  
clearday™ Beyond 1-day Toric  
clearday™ Beyond 1-day Multifocal**

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

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### IMPORTANT:

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### DESCRIPTION:

The **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** is available in spherical, toric and multifocal lens designs. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material (**Avefilcon A**), is composed of siloxane containing monomer and macromer. It is cross linked with other hydrophilic monomers and dimethacrylate cross linker. The lenses are incorporated with Reactive Blue 19, a US FDA approved dye for contact lens as handling tint. The **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** consists of 40% **Avefilcon A** and 60% water by weight when immersed in buffered saline solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it is to be maintained in a fully hydrated state in a solution compatible with the eye. If the lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and replace it with a fresh one.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state and the lens is approximately 60% water by weight.

The physical properties of the lens are:

Refractive Index	1.392
Light Transmission	> 95%
Surface Character	Hydrophilic
Water Content	60%
Oxygen Permeability	$88 \times 10^{-11}$ (cm <sup>2</sup> /sec) x (ml O <sub>2</sub> / [ml x mm Hg])

The lens Parameters are:

Spherical Power Range	-20.00 to +20.00D
Diameter Range	12.00 to 15.00 mm
Base Curve Range	7.80 to 10.00 mm

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The **clearday™ Beyond 1-day** Daily Disposable soft silicone hydrogel contact lenses are available in the following dimensions:

Diameter:	14.1 mm
Centre Thickness:	0.09 mm @-3.00D (varies with power)
Base Curve:	8.6 mm, 8.8 mm (for +4.00 to +6.00D)
Powers:	0.00 to -6.00 Dioptres in 0.25 D increment -6.50 to -10.00 Dioptres in 0.50 D increment +0.50 to +6.00 Dioptres in 0.25 D increment

The **clearday™ Beyond 1-day toric** Daily Disposable soft silicone hydrogel contact lenses are available in the following dimensions:

Diameter:	14.3 mm
Centre Thickness:	0.09 mm @-3.00D (varies with power)
Base Curve:	8.5 mm
Powers:	0.00 to -6.00 Dioptres in 0.25 D increment -6.50 to -8.00 Dioptres in 0.50 D increment +0.25 to +4.00 Dioptres in 0.25 D increment
Cylinder:	-0.75D, -1.25D, -1.75D, -2.25D
Axis:	10° to 180° (in 10° step)

The **clearday™ Beyond 1-day multifocal** Daily Disposable soft silicone hydrogel contact lenses are available in the following dimensions:

Diameter:	14.2 mm
Centre Thickness:	0.09 mm @-3.00D (varies with power)
Base Curve:	8.6 mm
Powers:	0.00 to -6.00 Dioptres in 0.25 D increment -6.50 to -8.00 Dioptres in 0.50 D increment +0.25 to +4.00 Dioptres in 0.25 D increment
ADD Powers:	+1.00D, +1.50D, +2.00D, +2.50D

### ACTIONS:

In its hydrated state, the **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens**, when placed on the cornea, acts as a corrective refracting medium (except for plano lenses) to focus light rays on the retina.

### CAUTION:

Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently when selecting an appropriate

lens design and parameter, the eyecare 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 must be carefully weighed against the patient's need for refractive correction. Therefore the continuing ocular health of the patient and the lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

**INDICATIONS (USES):**

The **clearday™ Beyond 1-day** Daily Disposable Soft Silicone Hydrogel Contact Lens is indicated for daily wear single use only for the optical correction (except for plano lenses) of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The **clearday™ Beyond 1-day toric** Daily Disposable Soft Silicone Hydrogel Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes.

The **clearday™ Beyond 1-day multifocal** Daily Disposable Soft Silicone Hydrogel Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new, unexpired lens.

**CONTRAINDICATIONS (REASONS NOT TO USE):**

**DO NOT USE the clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.

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- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- Advise patient not to wear **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** while sleeping.
- Patient with history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.

### WARNINGS:

- **PROBLEMS WITH CONTACT LENS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eyecare practitioner's direction and all labeling instructions for proper use of lens and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENS AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.**
- All contact lens wearers must see their eye care practitioner as directed.
- Daily wear lens are not indicated for overnight wear, and you are instructed not to wear the **clearday® Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lens are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.

### PRECAUTIONS:

#### Special Precautions for the Eyecare Practitioner:

- Always discard disposable lenses after the recommended wearing schedule prescribed by the eyecare practitioner.
- Consequently when selecting an appropriate lens design and parameter, the eyecare 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 must be carefully weighed against the patient's need for refractive correction. Therefore the continuing ocular health of the patient and the lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- Fluorescein, a yellow dye, should not be used while the lens is on the patient's eye. The lens absorbs this dye and becomes discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove the lens or should have someone else available to remove the lens for him or her.
- Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

**The eyecare practitioner should carefully instruct patients about the following lens care regimen and safety precautions:**

- If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to remove their lenses immediately and contact their eye care professional promptly. It is therefore recommended that contact lens wearers see their eye care professional routinely as directed.
- The lens is intended to be **WORN ONCE** and then discarded at the end of each wearing period.
- The patient should be instructed to start the next wearing period with a new, unexpired lens.
- Emergency lens cleaning and disinfection is not recommended.
- The patient should be reminded to have replacement lenses or back-up spectacles available at all times.
- The patient should be instructed to always have a spare pair of lenses at all times.
- Always wash and rinse hands before handling lens.
- Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens.
- It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal and wearing instructions in the patient instructions for the **clearday® Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** and those prescribed by the eyecare practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on care for 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.

- Never wear lens beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask the eyecare practitioner about wearing lens during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine or medications 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 lens.
- 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.

#### **ADVERSE REACTIONS:**

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- Unusual eye secretions.
- Redness of the eye.
- 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, the patient should **IMMEDIATELY REMOVE THE LENS!**

- If discomfort or problems stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON EYE.** Discard the lens and replace with a fresh lens.

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- After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. **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 the **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens**. For detailed description of the fitting techniques, refer to the **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens Professional Fitting Guide and Patient Information/ Wearer's Guide**, copies of which are available from:

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Website: [www.clearlab.com](http://www.clearlab.com)

### **RECOMMENDED WEARING SCHEDULE:**

Close professional supervision is recommended to ensure safe and successful contact lens wear. If any discomfort, decreased vision, ocular injection or corneal edema, is felt or experienced, the lens should be removed and the patient scheduled with their eye care professional for examination immediately. The problem may be relieved by establishing a different wearing schedule or possibly by refitting the lens.

### **THE WEARING AND REPLACEMENT SCHEDULE SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.**

It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This is to allow more gradual adaptation of the ocular tissues to contact lens wear. It is important not to exceed the wearing schedule. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check ups, as determined by the eye care practitioner, are also extremely important.

The **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** is indicated for daily wear. Normal daily wear of lenses assumes a



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minimum of 6 hours of non-lens wear everyday (i.e. for every 24 hours). The maximum suggested wearing schedule for the **clearday™ BEYOND 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** is suggested below:

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

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens**" IS SAFE TO WEAR DURING SLEEP. Patients should not sleep while wearing this product.

**PLANNED REPLACEMENT:**

The **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** is intended to be **WORN ONCE** and discarded upon removal. The patient should be instructed to start the next wearing period with a new, unexpired lens.

**LENS CARE DIRECTIONS:**

The **clearday™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** is intended to be worn once and discarded upon removal. The patient should be instructed to start the next wearing period with a new, unexpired lens.

Eyecare Practitioners should review with the patient lens care directions, including both basic lens care information and specific instruction on the lens care wearing schedule recommended for the patient.

**Dried out (dehydrated) dry lens:**

- If a lens becomes dehydrated while not on eye, it should be discarded. The discarded lens should be replaced with a fresh-sterile lens.

**Care for a sticking (non-moving) lens on Eye:**

- If the lens sticks (cannot be removed from eye), the patient should be instructed to apply 3 to 4 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 after 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

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Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

The patient should be informed that if any chemical of any kind (household products, gardening solutions, laboratory chemicals, etc) are splashed into the eyes, the patient should:

**FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

### HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is marked with dioptic for spherical lenses or toric power, cylinder axis for toric lenses, multifocal add for multifocal lenses, Rx symbol, sterile symbol, composition of the lens, manufacturing lot number and expiration date of the lens. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE'.

### REPORTING OF ADVERSE REACTION:

Practitioners should report any adverse reactions to **clearlab™ Beyond 1-day (Avefilcon A) Daily Disposable Soft Silicone Hydrogel Contact Lens** within 5 days to at the address below:

**Clearlab SG Pte. Ltd.**  
139 Joo Seng Road,  
Singapore 368362  
Tel: +65 6749 1090  
Fax: +65 6282 3953  
Email: [Regulatory@clearlab.com](mailto:Regulatory@clearlab.com)  
Website: [www.clearlab.com](http://www.clearlab.com)

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