PACKAGE INSERT

clearday® Beyond clearday® Beyond toric

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 the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

clearday® BEYOND and **clearday® Beyond toric (Avefilcon A) SOFT (hydrophilic) SILICONE HYDROGEL CONTACT LENS**

clearday® Beyond

and

clearday® Beyond toric

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

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DESCRIPTION:

The **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is available as a single vision spherical lens, and as a back surface astigmatic (toric) lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

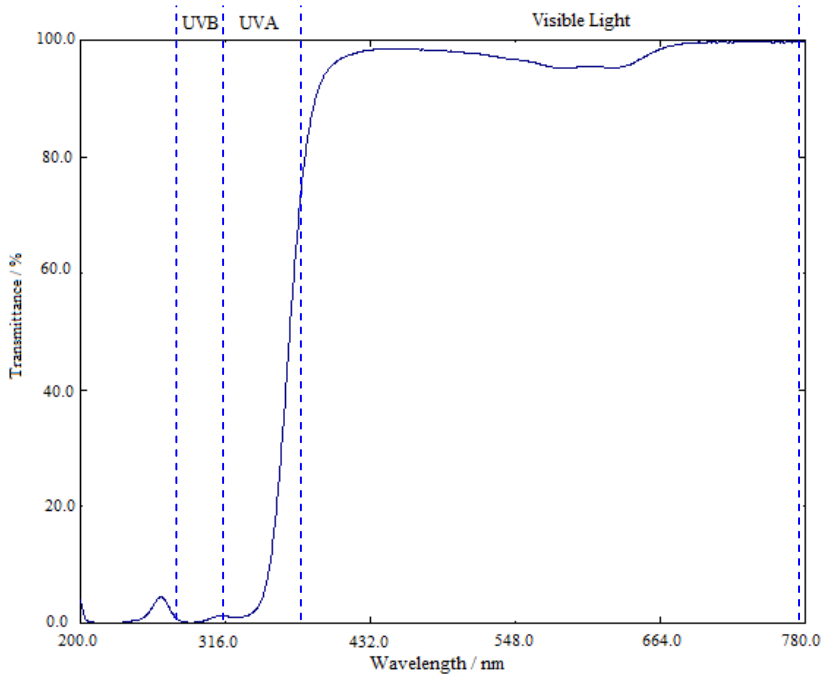
The non-ionic lens material (Avefilcon A) is composed of siloxane containing monomer and macromer. It is cross linked with other hydrophilic monomers and dimethacrylate cross linker. The lenses are incorporated with Reactive Blue 19, a US FDA approved dye for contact lens as handling tint. The **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** consists of 40% Avefilcon A and 60% water by weight when immersed in buffered saline solution. This contact lens contains a UV blocking material that blocks UVB and UVA radiation. A -3.00D lens with center thickness of 0.06mm blocks about 96% of UVB rays and about 55% of UVA rays.

UV radiation blockage provided by **clearday ™ BEYOND** and **clearday® Beyond toric (Avefilcon A**) will increase for thicker lenses.

WARNING:
UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such sunglasses, because they do not completely cover the eye and surrounding area. Patients should continue to use UV-absorbing eyewear as directed by a licensed eye care professional.

Figure 1:

Representative UV transmittance profile of -3.00D clearday ™ BEYOND (**Avefilcon A**) contact lens.



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 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, becomes dry 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 the lens is approximately 60% water by weight. The physical properties of the lens are:

Refractive Index	1.397
Light Transmission	95%
Water Content	60 %
Oxygen Permeability	88 x 10^{-11}(cm ^{2}/sec) x (ml O_2 / [ml x mm Hg]) @ 35 ^{o}C

The lenses are hemispherical flexible shells which cover the cornea and portion of the adjacent sclera with the following dimensions:

Chord Diameter	:	12.00 – 15.00 mm
Base Curve	:	7.80 – 10.00 mm
Center Thickness	:	0.04 – 0.80 mm
Powers	:	0.0 to -6.00 Diopters(D) in 0.25D increment -6.50 to -20.00 Diopters(D) in 0.50D increment +0.25 to +4.00 Diopters(D) in 0.25D increment +4.50 to +20.00 Diopters(D) in 0.50D increment
Cylinders	:	-0.75D, -1.25D, -1.75D, -2.25D
Axis	:	10° to 180° in 10° increment

ACTIONS:

In its hydrated state, the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** when placed on the cornea, act as a refracting media (except for plano lenses) to focus light rays on the retina.

CAUTION:
Due to the small number of patients enrolled in clinical investigation of this lens, 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 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.

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 lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

INDICATIONS:

The **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** for daily wear contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **clearday® Beyond (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is indicated for the optical correction (except for plano lenses) of ametropia (myopia or hyperopia) in aphakic and non-aphakic persons with non-diseased eyes within the limits of the product specification. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.

The **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is indicated for the optical correction (except for plano lenses) of

ametropia (myopia or hyperopia) in aphakic and non-aphakic persons with non-diseased eyes within the limits of the product specification. The lens may be worn by persons who exhibit refractive astigmatism of 7.00D diopters or less.

The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Eye care practitioners may prescribe the lenses for frequent/ planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/ planned replacement wear, the lens is to be cleaned, rinsed and disinfected, each time it is removed from patient's eye, with an approved chemical (not heat) lens care system.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** when any of the following conditions exist:

- 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.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**.
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- Patient 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 AND LENS CARE PRODUCTS COULD RESULT IN **SERIOUS INJURY** TO THE EYE. It is essential that patients follow their eye care 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 EYE CARE PRACTITIONER.

- All contact lens wearers must see their eye care practitioner as directed.

- Daily wear lens are not indicated for overnight wear, and patients should be instructed not to wear lens while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when this lens is 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 eye care practitioner:

- Clinical study is still on going for evaluation. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.
  Consequently, 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.

  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.
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorbs this dye and become 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 eye care practitioner's office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.

- Eye care practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following 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.

- Different solutions cannot always be used together, and not all solutions are safe for use with all lens. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used should be discarded after the time specified in the labeling directions.

- Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for care for a dried out (dehydrated) dry lens if the lens surface does become dried out.

- 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.

- 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 microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** and those prescribed by the eye care practitioner.

- Never wear lens beyond the period recommended by the eye care 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 eye care 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 eye care 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 schedule.
- The patient should discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule as prescribed by the eye care professional.
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced on a regular basis (at a regular interval) as recommended by the lens case manufacturer or eye care professional.

ADVERSE REACTIONS:

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 you notice any of the above, **IMMEDIATELY REMOVE YOUR 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 YOUR EYE**. Place the lens in the storage case and contact your eye care practitioner.

- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lens, then reinsert them.

- After reinsertion, if the problem continues, you should **IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYE CARE PRACTITIONER**.

- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. KEEP 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 lens apply to the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**. For a detailed description of the fitting techniques, refer **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** Professional Fitting and Patient Information/ Wearer's Guide, copies of which are available from:

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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.

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. Regular check ups, as determined by the eye care practitioner, are also extremely important. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear everyday (i.e. for every 24 hours). The maximum suggested wearing schedule for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** is suggested below.

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

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE "clearday® Beyond and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens" IS SAFE TO WEAR DURING SLEEP. Patients should not sleep while wearing this product.**

FREQUENT / PLANNED REPLACEMENT:

It is recommended that the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** be discarded and replaced with a new lens after 30 days. When removed between replacement periods lenses must be cleaned and disinfected prior to reinsertion, or be discarded and replaced with a fresh lens. However, patients should adhere to the recommended replacement schedule given by their eye care professional based upon their individual needs and physiological conditions.

LENS CARE DIRECTIONS:

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

Basic Instructions:

Care of contact lens takes very little time and involves THREE essential steps - **CLEANING, RINSING AND DISINFECTING.** Each step in itself is important, and one step is not to be replaced by the other.

- Always wash, rinse and dry hands before handling contact lens. Inspect fingers and hand to ensure they are free of fibers or other debris.
- Always use **FRESH, STERILE UNEXPIRED** lens care solutions.
- Use the recommended lens care system; either chemical (not heat) or heat (thermal).
- Different solutions cannot always be used together, and not all solutions are safe for use with all lens. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- The eye care practitioner should recommend a care system that is appropriate for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lens while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Lens cleaning, disinfection, and storage:

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, **disinfect** lens using the system recommended by the manufacture and/or the eye care practitioner.
- To store lens, disinfect and leave them in the closed/unopened case until ready to wear. The lenses should not be removed from the case until they have been disinfected for the amount of time specified by the lens care solution instructions. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lens. Follow the instruction and timing recommended by the solution manufacturer.

Lens Case Cleaning and Maintenance:

- Contact lens cases can be a source of bacteria growth.
- After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; then allow the lens case to air dry.
- When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

Lens Care Regimen:

- Patients must adhere to the lens care regimen recommended by their eye care practitioner for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**.
- Failure to follow this procedure may result in development of serious ocular infections

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.

Storage:

- The **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** must be stored only in the recommended solutions.
- If left exposed to the air, the lens will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lens.

Lenses prescribed for frequent replacement:

- The **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** may be prescribed in a frequent replacement program and should be thrown away after the recommended wearing period prescribed by the eye care practitioner.

Chemical (NOT HEAT) Lens Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, **CLEAN** the lens by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells for a minimum of 4 hours. Follow the instruction and timings recommended by the manufacturer.

   Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.
   Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER:

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of the patient's lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS:

The eye care practitioner should recommend a care system that is appropriate for the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic)**

Silicone Hydrogel Contact Lens. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

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 EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied sterile in blister packs in phosphate buffered saline. The blister pack is marked lens base curve, diameter, dioptric power, manufacturing lot number, expiration date, Single Patient Use, Rx symbol, sterile symbol and composition of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **clearday® Beyond** and **clearday® Beyond toric (Avefilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens** or experienced with the lens should be reported to:

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