

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.








clear1-day (HIOXIFILCON A) DAILY DISPOSABLE SOFT CONTACT LENS (VISIBILITY TINT)
















clear1-day spherical
clear1-day toric
clear1-day multifocal

Symbols key

The table shows the symbols that may appear on label or carton

Symbol	Description
	CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Licensed Eye Care Practitioner.
	Sterilized using steam or dry heat
	Caution
	Do not use if package is damaged and consult instructions for use
	Manufacturer
	Date of manufacture
	Authorized Representative in European Community

Symbol	Description
D	Diopter (Lens Power)
	Temperature limits
	Do not resterilize
	Medical Device
	Catalogue number
	Model number
	Unique Device Identifier

	Batch code (Lot number)
	Use by date (Expiry date)
	Consult instructions for use or consult electronic instructions for use
	European conformity sign
	Base Curve
	Diameter
	Importer

	Single sterile barrier system
	Keep dry
	Keep away from sunlight
	Fragile, Handle with care
	Do not reuse
	Recyclable material

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

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DESCRIPTION OF LENS:

The **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lenses** are 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.

Material Characteristics:

The non-ionic lens material, (Hioxifilcon A) is a random co-polymer of 2-hydroxyethyl methacrylate and glycerol methacrylate cross-linked with ethylene glycol dimethacrylate. It consists of 42% Hioxifilcon A and 58% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, color additive 'Reactive Blue 4' 21 CFR Part 73.3121. The Hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

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 dries out, it will become hard and appear somewhat wrapped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allows aqueous solutions to enter the lens and in its fully hydrated state and the lens are approximately 58% water by weight.

The physical properties of the lens are:

Refractive Index	1.4011(wet)
Light Transmission	> 95%
Surface Character	Hydrophilic & non-ionic nature
Water Content	58% (±2.0%)
Oxygen Permeability	25.38 x 10 ⁻¹¹ (cm ² /sec) (mlO ₂ /ml x mmHg), (revised FATT method) for Spherical Lens
	25 x 10 ⁻¹¹ (cm ² /sec) (mlO ₂ /ml x mmHg), (revised FATT method) for Toric Lens & Multifocal lens

The **clear1-day (spherical)** Daily Disposable soft contact lenses are available in the following dimensions:

Diameter:	14.00mm to 14.40 mm
Centre Thickness:	0.090 ± 0.020 mm @ -3.00D (varies with power)
Base Curve:	8.60mm to 9.00mm (for power range of +4.00D to +6.00D)
	8.50mm to 8.90mm (for power range of -10.00D to +3.75D)
Powers:	+0.25D to +6.00D in 0.25 D increment
	0.00D^ to -6.00 D in 0.25 D increment
	-6.50D to -10.00 D in 0.50 D increment

The **clear1-day Toric** Daily Disposable soft contact lenses are available in the following dimensions:

Diameter:	14.20mm to 14.60mm
Centre Thickness:	0.110 mm ± 0.020 mm @-3.00D (varies with power)
Base Curve:	8.30mm to 8.70 mm
Powers:	+4.00D to +0.25D in 0.25 D increment 0.00D [^] to -6.00D in 0.25 D increment -6.50D to -10.00D in 0.50 D increment +4.50D to +6.00D in 0.50D increment
Cylinder:	-0.75D, -1.25D, -1.75D, -2.25D
Axis:	10° to 180° (in 10° step)

The **clear1-day multifocal** Daily Disposable soft contact lenses are available in the following dimensions:

Diameter:	14.00 mm to 14.40mm
Centre Thickness:	0.090 mm ± 0.020 mm @-3.00D (varies with power)
Base Curve:	8.50mm to 8.90mm
Powers:	+6.00D to +0.25D in 0.25 D increment 0.00D [^] to -6.00D in 0.25 D increment -6.50D to -10.00D in 0.50 D increment
ADD Powers:	+1.00D, +1.50D, +2.00D, +2.50D

[^]Note: Plano lens (0.00D – without corrective power) is not being sold in EU. Plano lens is used for the manufacture of cosmetically tinted lenses (colored lenses). Standard Minus Power SKU starts at -0.25D.

ACTIONS:

In its hydrated state, the **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens**, when placed on the cornea, acts as a corrective refracting medium (except for plano lenses) to focus light rays on the retina.

INDICATIONS (USES):

The **clear1-day (spherical)** Daily Disposable Soft 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 and aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The **clear1-day Toric** Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic and aphakic persons with non-diseased eyes who may have 7.00D or less of astigmatism.

The **clear1-day Multifocal** Daily Disposable Soft 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 and 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 lens. Reusing daily disposable contact lenses can increase the risk of infection, dryness, and discomfort.

The target population for the use of this device are adults of 18 years or older. There is no clinical data to support the use of this device by individuals under 18 years of age. Use of this device by individuals less than 18 years of age is at the sole discretion of the eye care professionals (ECP).

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clear1-day (Hioxifilcon A) Daily Disposable Soft 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.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- Advise patient not to wear **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens** while sleeping.

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.

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.**
- Daily wear lens is not indicated for overnight wear, and you are instructed not to wear the **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens** while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight. Patients are advised to remove lenses while sleeping.
- 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**

Clinical studies have demonstrated that the contact lenses manufactured from (Hioxifilcon A) are safe and effective for their intended use. However, the clinical studies may not have included all the design configurations or lens parameters that are presently available in this lens material.

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:

- 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 lens.
- Emergency lens cleaning and disinfection is not recommended.
- The patient should be reminded to always have replacement lenses or back-up spectacles available.
- The patient should be instructed to always have a spare pair of lenses.
- 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.
- Insert lenses before applying makeup and remove lenses before taking makeup off.
- 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 **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens** and those prescribed by the eyecare 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.
- Avoid wearing contact lens during swimming activities. Chemicals from treated water may be absorbed by the contact lens and alter its physicochemical properties; chemical residues or foreign materials may stick or deposit on the surface of the lens and will cause eye irritation, inflammation, or injury to the eye. Swimming in untreated water may cause bacteria or fungus to stick on the surface of the contact lens causing eye infections.

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, he or she should be instructed to:

- **IMMEDIATELY REMOVE THE LENS.**
- If discomfort or problems stops, then look closely at the lens. If the lens is in a way damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Discard the lens and replace with a fresh lens.
- **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 **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens**. For detailed description of the fitting techniques, refer to the **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens Professional Fitting Guide**, copies of which are available from:

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PERSONAL CLEANLINESS and LENS HANDLING:

Cleanliness is an important aspect of contact lens care.

Before Handling Your Lens:

- Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel.
- Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands.
- Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens.
- When hair spray is used, the eye must be kept closed until the spray has settled.
- Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects.
- NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

Handling and Placing the Lens on the Eye:

- To avoid the possibility of lens mix-ups, always start with the same lens first.
- Remove the Lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Place the lens on the tip of the index finger of your dominant hand.
- While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- Look straight ahead and raise the upper lid with your other index finger.
- Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- Slowly release upper lid, and gently close your eye.
- The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.

- Repeat the above procedure for the second lens.
- If the lens does not move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens placement difficult, your eyecare practitioner will suggest another method or provide additional information.

NOTE: If after replacement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the lens" next in this booklet.
- If the lens is centered, remove the lens (see "Removing the lens" section) and check the following:
 - a. Cosmetic or oils on the lens. Discard lens and place a new lens on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens inside-out (it would also not be as comfortable as normal)

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare practitioner.

Centering the Lens:

Very rarely a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedure outlined below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If the lens gets under the upper lid, gently massage the upper lid while looking down and move the lens toward the cornea.

Removing the Lens from the Eye:

Preparation:

- Wash and rinse your hands thoroughly.
- Dry hands with a lint-free towel.
- Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

Removal:

- To avoid the possibility of lens mix-ups, always begin with the same lens.
- Look up and keep both eyes open.

- Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- Gently "pinch" the lens between the index finger and the thumb and remove.
- Repeat the procedure for the second eye.
- If the lens still cannot be moved, contact your eyecare practitioner for further instruction.
- Upon removal, discard the lens.

IMPORTANT:

Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or provide additional instruction.

WEARING SCHEDULE:

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

The lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the lens initially. 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 eyecare practitioner, are also extremely important.

The **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens** are indicated for daily wear. The maximum suggested wearing time for the **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact Lens** is:

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

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER

PLANNED REPLACEMENT:

The **clear1-day (Hioxifilcon A) Daily Disposable Soft Contact 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 lens.

CARING FOR YOUR LENS:**Basic Instructions:**

The **clear1-day® (Hioxifilcon A) Daily Disposable Soft Contact Lens** described in this booklet is designed as a Daily Disposable lens.

The lens is intended to be worn once and then discarded at the end of each wearing period. You are instructed to start the next wearing period with a new lens. You are also instructed to always have a spare pair of lenses with you.

The lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the lenses initially. The eyecare professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that **clear1-day® (Hioxifilcon A) Daily Disposable Soft Contact Lens** are safe to wear during sleep; therefore, patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours non-lens wear per 24-hour period. Optimum individual wearing schedule will vary.

You should adhere to a recommended daily disposable care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the warning section above.

If you require only vision correction but will not or cannot adhere to a recommended care regimen for your lens, or unable to place and remove your lens or have someone available to place and remove them, you should not attempt to get and wear contact lens.

When you first get your lens, be sure you must put the lens on and remove them while you are in your eyecare practitioner's office.

Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use and provide you with a copy of the Wearer's Guide for the **clear1-day® (Hioxifilcon A) Daily Disposable Soft Contact Lens**.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lens.
- Do not use saliva for lubricating or rewetting lens. Do not put lens in the mouth.

STORAGE CONDITIONS:

Store lenses between 23°C to 27°C.

EMERGENCIES:

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.

WHEN TO CALL YOUR PRACTITIONER?

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eyecare practitioner if:

- Your eye becomes red and feels irritated or "gritty".
- You notice a change in your vision or see rainbows or halos around objects.
- You experience discomfort and/ or sensitivity to lights.

A good general policy is:

"IF IN DOUBT ... TAKE THE LENS OUT" and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

- Follow Instructions.
- Handle Lens Properly.
- Learn How to Put on and Take Off Your Lens.
- Always use a fresh lens at the start of the wearing period.

INSTRUCTIONS FOR MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches, and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that

you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

HOW SUPPLIED:

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

DISPOSAL

There is no special disposal required for soft contact lens and its blister. The carton packaging, aluminum lidding and polypropylene (PP) plastic case should be placed properly in the waste bin or recycled according to local waste guidance or local regulations.

REPORTING OF ADVERSE REACTION:

All serious adverse experiences and adverse reactions observed in patients wearing this contact lens or experienced with the lens should be reported to the manufacturer and the competent authority of the member state.

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