

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.

Clear38™ (POLYMACON A) DAILY WEAR SOFT (HYDROPHILIC) SPHERICAL CONTACT LENS (VISIBILITY TINT WITH UV BLOCKER)



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 the product sterile barrier system or its packaging is compromised.
	Manufacturer
	Date of Manufacture
	Authorized Representative in European Community
	Batch code (Lot number)
	Use by date (Expiry date)
	Consult instructions for use.
	European Conformity Sign
BC	Base Curve
DIA	Diameter
D	Diopter (Lens Power)
	Temperature limits

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



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DESCRIPTION:

The **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** is available in a single vision spherical 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, (Polymacon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethylene glycol demethacrylate. It consists of 62% Polymacon A and 38% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visibility-handling tint, color additive 'Reactive Blue 19', 21 CFR part 73.2121. The Polymacon A name has been adopted by the United States Adopted Names Council (USAN).

In the **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens with UV Blocker**, 2-(4-Benzoyl-3-Hydroxyphenoxy) Ethyl Acrylate (BHPEA) is used to block UV radiation. The UV blocking for **clear38™** averages < 30% in the UVB range of 280nm - 315nm and <70% in the UVA range of 316 - 380nm.

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

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.43 (hydrated)
Light Transmission	>90% over the visible spectrum
Water Content	38 %
Specific Gravity	1.15 (hydrated)
Oxygen Permeability	12.92 x 10 ⁻¹¹ (cm ² /sec) (mLO ² /ml x mm Hg @ 35 ⁰ C)

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

Chord Diameter	12.00mm to 16.00mm
Center Thickness	0.097mm @ -3.00D
Base Curve	7.00mm to 10.00mm
Powers	-20.00 Diopters to +20.00 Diopters

ACTIONS:

In its hydrated state, the **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

CAUTION:

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers.

Consequently, when selecting an appropriate lens design and parameters, the eye care 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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** for daily wear contains a UV Broker to help protect against transmission of harmful UV radiation to the cornea and into the eye. It is indicated for the correction of visual acuity (except for plano lenses) in phakic and aphakic person with non-diseased eyes who have myopic or hypermetropic vision. The lens (except for plano lenses) may be worn by persons who exhibit refractive astigmatism of 2.00 dioptres or less where the astigmatism does not interfere with visual acuity. The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Eyecare practitioners may prescribe the lens 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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical 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.

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- 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 lens.
- Any active corneal infection (bacteria, 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 is 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, such as ulcerative keratitis 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 studies have demonstrated that contact lens manufactured from (Polymacon A) is safe and effective for their intended use. 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:

- 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. 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 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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** as those prescribed by the eye care practitioner.
- Never wear lens beyond the period recommended by the eye care practitioner.

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- 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.

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 LENS.**
- If discomfort or problems stops, then look closely at the lens. **If** the lens is in any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the 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, the patient should thoroughly clean, rinse, and disinfect the lens then reinsert them.
- After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS AND CONSULT THE EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to

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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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens**. For a detailed description of the fitting techniques, refer **clear38™ (Polymacon A) Soft (Hydrophilic) Spherical Contact Lens Professional Fitting Guide and Patient Instruction/ Wearer’s Guide**, copies of which are available from:

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WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lens initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

The **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** is indicated for daily wear. The maximum suggested wearing time for this lens is:

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 clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens IS SAFE TO WEAR DURING SLEEP.

- WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

FREQUENT/ PLANNED REPLACEMENT:

It is recommended that the **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** be discarded and replaced with a new lens monthly. 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 MM 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 clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and followed carefully.
- 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

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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. 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 disinfection with Hydrogen Peroxide lens care systems:

- **Neutralized the lens before wearing, when hydrogen peroxide lens care systems is used** and carefully follow instructions on solution labeling.
- **Use ONLY the lens case provided with the hydrogen peroxide care system** as this case may contain neutralizer. Failure to use the specialized case will cause stinging, burning, and damage to the eye. Always follow the recommendations on hydrogen peroxide lens care system labeling.

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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens**.
- Failure to follow this procedure may result in development of serious ocular infections.

Care for a dried out (dehydrated) dry lens:

- If for some reason, your lens dry out completely a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and

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disinfecting procedures - including soaking the lens in storage and disinfection solution for four hours before wearing again.

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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical 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 **clear38™ (Polymacon A) Soft (hydrophilic) Spherical 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:

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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 eyecare practitioner should recommend a care system that is appropriate for the **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

STORAGE CONDITIONS:

Store lenses between 1°C to 45°C.

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 containing buffered normal saline solution. The blister pack is marked with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **clear38™ (Polymacon A) Soft (hydrophilic) Spherical Contact Lens** or experienced with the lens should be reported to:

Clearlab SG Pte. Ltd.

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Email: Regulatory@clearlab.com

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Clearlab SG Pte. Ltd.

Printed in Singapore

Revision Date: Oct 2020

Doc Number: S-ASP-064-A

Version Number: V05

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