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clear1-day®

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.

clear1-day® (HIOXIFILCON A) DAILY DISPOSABLES SOFT CONTACT LENS(CLEAR AND VISIBILITY TINT)

clear1-day®

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

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DESCRIPTION:

The **Clear1-day® Daily Disposables** soft contact lens is available as 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, (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 warped 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 is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index at 21°C	1.4011(wet)
Light Transmission	> 95%
Surface Character	Hydrophilic
Water Content at 21°C	59.77%
Specific Gravity at 21°C	1.086(wet)
Oxygen Permeability at 34-36 °C	25.38 (cm ² /sec)(mlO ₂ /ml x mmHg), (revised FATT method)

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

Chord Diameter:	14.2 mm
Centre Thickness:	0.09 mm
Base Curve:	8.7 mm
Powers:	+6.00 to +0.50 Dioptres in 0.25 D increment -0.50 to -6.00 Dioptres in 0.25 D increment -6.50 to -10.00 Dioptres in 0.50 D increment

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ACTIONS:

In its hydrated state, the **clear1-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens**, when placed on the cornea, acts as a corrective refracting medium 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:

The **clear1-day® (Hioxifilcon A) Daily Disposables 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 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.

At the sole discretion and under the direct supervision of a qualified and licensed eye care professional, the lenses are also indicated for therapeutic use as a bandage to protect the cornea and to relieve corneal pain in the treatment of acute or chronic ocular pathologies, such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post surgical conditions resulting from cataract extraction and corneal surgery.

At the sole discretion and under the direct supervision of a qualified and licensed eye care professional, these lenses with cosmetic effects such as tints are also intended for use as prosthetic device for sighted and non-sighted eyes, with or without lens power.

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CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clear1-day® (Hioxifilcon A) Daily Disposables 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 Disposables Soft Contact Lens** while sleeping.

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 are not indicated for overnight wear, and you are instructed not to wear the **clear1-day® (Hioxifilcon A) Daily Disposables Soft 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

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

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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 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.

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- Carefully follow the handling, insertion, removal and wearing instructions in the patient instructions for the **clear1-day® (Hioxifilcon A) Daily Disposables 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.

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**

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continues, you should IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.

- **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 Disposables Soft Contact Lens**. For detailed description of the fitting techniques, refer to the **clear1-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens Professional Fitting Guide**, copies of which are available from:

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139 Joo Seng Road,

Singapore 368362

Tel: +65 6749 1090

Fax: +65 6282 3953

Email: Regulatory@clearlab.com

Website: www.clearlab.com

WEARING SCHEDULE:

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

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

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

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STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE **clear1-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens** IS SAFE TO WEAR DURING SLEEP

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER

PLANNED REPLACEMENT:

The **clear1-day® (Hioxifilcon A) Daily Disposables 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.

LENS CARE DIRECTIONS:

The **clear1-day® (Hioxifilcon A) Daily Disposables 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.

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.

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.

REPORTING OF ADVERSE REACTION:

Practitioners should report any adverse reactions to **clear1-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens** within 5 days to at the address below:

Additional Professional Fitting Guide and Patient Instruction/ Wearer's Guide are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com

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Website: www.clearlab.com

HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is marked with dioptric power, Single Patient Use, 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'.

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