

**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.

**DAILY DISPOSABLE (Hioxifilcon A) COLOR SOFT CONTACT LENS**

clearcolor™ 1-day  
and  
Aryan™ color 1-day

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

clearlab™

*Trademarks used in this document are owned by Clearlab SG Pte. Ltd. Except otherwise stated, all the trademarks indicated as registered in this document are registered in Singapore and may also be registered in other jurisdictions.*

**DESCRIPTION**

This **Soft Hydrophilic Daily Disposable Color 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. This **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** is fabricated from a nonionic polymer.

This **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** is made of a nonionic lens material, Hioxifilcon A, which is a random co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and glycerol methacrylate (HEMA/GMA) cross-linked with ethylene glycol dimethacrylate. The co-polymer consists of 42% Hioxifilcon A and 58% water by weight when immersed in normal buffered saline solution. The Hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

The lenses are available tinted. Lenses are tinted with one or a combination of one or more of the following pigments, 'listed' color additives: C.I. Reactive black 5, C.I. Vat orange 5, Iron oxides, C.I. Pigment green 7, C.I. Vat brown 1, C.I. Vat yellow 3, C.I. Vat blue 6, C.I. vat orange 1, C.I. Vat green 1, C.I. Pigment blue 36, C.I. Pigment violet 23, D&C Green No.6, phthalocyanato (2) copper, D&C Yellow No.10, D&C Red No.17 and Titanium dioxide. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended cosmetic effect.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (Hioxifilcon A) soft hydrophilic contact lens has a spherical back 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.

Chord Diameter:	12.8 mm to 15.0 mm
Center Thickness:	.080 mm to .266 mm
Base Curve:	8.0 mm to 9.4 mm
Spherical Powers (spherical lens)	-10.00 Diopters to +6.00 Diopters

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index	1.4011 (hydrated)
Light Transmission (tinted)	greater than 95%
Water Content	58% ± 2%
Oxygen Permeability	25.38 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C), (revised Fatt method).

## **ACTIONS**

In its hydrated state, this **Soft Hydrophilic Daily Disposable Color Soft Contact Lens**, when placed on the cornea, act as a corrective 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**

This **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** (except plano lens) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes 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.

## **CONTRADICTIONS (REASONS NOT TO USE)**

**DO NOT USE** this **Soft Hydrophilic Daily Disposable Color 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.

- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care this **Soft Hydrophilic Daily Disposable Color Soft 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.
- Advice patient not to wear this **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** while sleeping.

## 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 EYECARE 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 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 nonsmoker do.

## PRECAUTIONS

### Special Precautions for eye care practitioner

- Clinical studies have demonstrated that contact lens manufactured from (Hioxifilcon 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.

Always discard disposable lenses after the recommended wearing schedule prescribed by the eye care practitioner.

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:

- 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.
- 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 and wearing instructions in the patient instructions for this **Soft Hydrophilic Daily Disposable Color Soft 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 h e s 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 **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 this **Soft Hydrophilic Daily Disposable Color Soft Contact Lens**. For a detailed description of the fitting techniques, refer to this **Soft Hydrophilic Daily Disposable Color Soft Contact Lens Professional Fitting and Information Guide**, copies of which 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](mailto:Regulatory@clearlab.com)  
Website: [www.clearlab.com](http://www.clearlab.com)

**WEARING SCHEDULE**

**THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE 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.

This **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** is indicated for daily wear. The maximum suggested wearing time for this lens is:

<u>DAY</u>	<u>HOURS</u>
1	6
2	8
3	10
4	12
5	14
6	All Waking hours*

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THIS SOFT HYDROPHILIC DAILY DISPOSABLE COLOR SOFT CONTACT IS SAFE TO WEAR DURING SLEEP.**

\* WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

**PLANNED REPLACEMENT**

This **Soft Hydrophilic Daily Disposable Color 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**

This **Soft Hydrophilic Daily Disposable Color 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.

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:

**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 EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**HOW SUPPLIED:**

Each lens is supplied sterile in a sealed blister pack 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. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE'.

**REPORTING OF ADVERSE REACTIONS**

All serious adverse experiences and adverse reactions observed in patients wearing this **Soft Hydrophilic Daily Disposable Color Soft Contact Lens** or experienced with the lens should be reported to:

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

**PACKAGE INSERT**

clearcolor™ 1-day  
*Aryan*™ color 1-day

**CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.**

clearlab™

Clearlab SG Pte. Ltd.

Printed in Singapore

Revision Date: Dec 2015

Doc Number: S-ASP-068-A

Version Number: 04

© 2015 CLEARLAB SG PTE. LTD. All Rights Reserved.