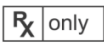










**Package insert for
Horien Monthly Color Contact Lens**

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 patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lens.

The following symbols may appear on the label or carton

Symbol	Definition
	Caution: Federal (USA) law restricts this device to sale by the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat
	Manufacturer
	Quality System Certification Symbol
	Package material and recycling symbol
	Lens contains UV blocking monomer
PWR	Power (in diopters) for contact lens
BC	Base Curve
DIA	Diameter

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

Table of Content

1.	GLOSSARY OF TERMS	3
2.	DESCRIPTION.....	4
3.	ACTIONS	5
4.	INDICATIONS FOR USE.....	5
5.	CONTRAINDICATIONS (REASONS NOT TO USE)	5
6.	WARNING	6
7.	PRECAUTIONS	6
8.	ADVERSE REACTIONS	7
9.	FITTING.....	8
10.	LENS REPLACEMENT / WEARING SCHEDULE	8
11.	LENS CARE DIRECTIONS	8
12.	CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):.....	10
13.	CARE FOR A DRIED OUT (DEHYDRATED) LENS	10
14.	CARE FOR A STICKING (NONMOVING) LENS.....	10
15.	EMERGENCIES	10
16.	HOW SUPPLIED	11
17.	REPORTING OF ADVERSE REACTIONS.....	11

1. GLOSSARY OF TERMS

Words that are explained below are identified at each occurrence in the text by highlighting with bolding.

Terms	Definition
Adnexa	Tissue surrounding the eyeball.
Ametropia (myopia)	Nearsightedness. A condition where the eyeball is too long and steep, so that light rays focus before they reach the retina. The result is difficulty in seeing distant objects clearly.
Anterior chamber	The anterior chamber (AC) is the fluid-filled space inside the eye between the iris and the cornea's innermost surface.
Aphakic	Absence of the crystalline lens of the eye.
Aspheric lens / Asphere	Contact Lens with its front or back optic zone of aspheric form.
Astigmatism	A condition where the cornea is irregularly shaped, causing distorted vision especially at near distances.
Conjunctiva	The membrane lines the inside of the eyelids and covers the sclera (white part of the eye).
Cornea	The cornea is the transparent front part of the eye that covers the iris, pupil, and anterior chamber.
Corneal ulcer	A corneal ulcer is an open sore or lesion on the cornea.
Daily wear	Worn during waking hours and removed at the end of each day for cleaning and disinfecting.
Disinfection	A process that kills harmful microorganism (germs) which can cause serious eye infection.
Iritis	Inflammation of the colored part of the eye (Iris).
Neovascularization	Blood vessel growing into the cornea.
Subacute inflammation	Gradual swelling, redness and pain.
Ulcerative Keratitis	An infected corneal ulcer.
UV (ultraviolet)	Light from the sun that can be harmful to the eye.

2. DESCRIPTION

Horien Monthly Color Contact Lens are available as **aspheric** lens design.

The lens material, polyacon, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). The lenses contain a benzophenone UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light. The average transmittance characteristics are less than 5 % in the UVB range of 280 to 315 nm and less than 50 % in the UVA range of 316 to 380 nm. The lenses are clear or tinted from edge to edge for visibility purposes with the color additive C.I. Reactive Blue No. 4 and printed with an intermittent coating containing a combination of approved color additives. Each finished lens is supplied in a plastic blister container with a sterile isotonic phosphate buffered saline solution containing wetting agents.

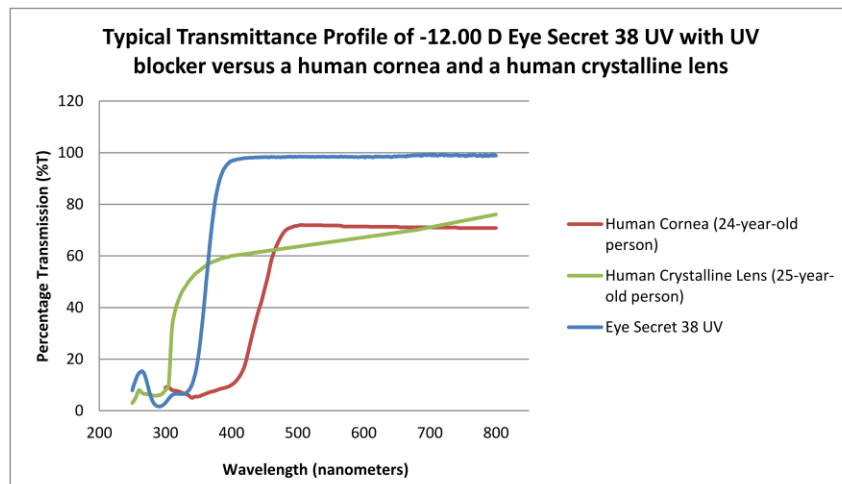
Horien Monthly Color Contact Lens are hemispherical shells of the following parameters:

- Diameter: 12.0~15.0 (± 0.2 mm)
- Basic Curve: 7.85~10.00 (± 0.2 mm)
- Center Thickness: 0.06 mm to 0.11 mm (varies with power)
- Powers: +20.00 D to -20.00 D

The physical/optical properties of the lens are:

- Refractive Index: $1.440 \pm 0.005 n_d$
- Light Transmittance: > 95 %
- Surface Character: Hydrophilic
- Water Content: 38 %
- UV transmittance: UVB < 5 %, UVA < 50 %
- Oxygen Permeability (Dk)* : $13.5 \pm 20\% \times 10^{-11}$

*(cm^2/sec)(ml $\text{O}_2/\text{ml} \times \text{mmHg}$) 35°C (Polarographic method for determination of oxygen permeability)



1. Human cornea from a 24 year-old person as described in Lerman, S., Radiant Energy

and the Eye, New York, 1980, p. 58, Figure 2-21.

2. Human crystalline lens from a 25 year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.
3. The UV lenses (Eye Secret 38 UV).

* The data was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens (-12.00 D, 0.060 mm center thickness) and measured according to ISO 18369-3:2006 – Ophthalmic optical – Contact Lenses – Part 3: Measurement methods.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

3. ACTIONS

When placed on the **cornea** in its hydrated state, Horien Monthly Color Contact Lens act as refracting media to focus light rays on the retina. The UV absorbing monomer in Horien Monthly Color Contact Lens is used to block UV radiation. The average transmittance characteristics are less than 5 % in the UVB and less than 50 % in the UVA.

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

4. INDICATIONS FOR USE

The Horien Monthly Color Contact Lens is indicated for the correction of refractive **ametropia (myopia or hyperopia)** in **aphakic** and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit **astigmatism** of 2.00 diopters or less that does not interfere with visual acuity. The Horien Monthly Color Contact Lens help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care professionals may prescribe the lens for **daily wear** in Monthly Replacement Program (see **Lens Replacement** for a description of the wearing schedule). The lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

5. CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use the Horien Monthly Color 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 lenses.
- Allergic reactions of ocular surfaces or **adnexa** that may be induced or exaggerated by wearing contact lenses 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 Horien Monthly Color Contact Lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.

6. WARNING

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including **corneal ulcers**, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of **ulcerative keratitis** is greater for extended wear contact lens users than for daily wear users.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of **ulcerative keratitis** is greater than among those who do not wear them overnight.
- The overall risk of **ulcerative keratitis** may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of **ulcerative keratitis** among contact lens users who smoke is greater than among non-smokers.
- If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

7. PRECAUTIONS

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be sure that before leaving the eye care professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.

- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Instruction Booklet for the Horien Monthly Color Contact Lens and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Contact lenses, even if worn for cosmetic reasons only, are prescription medical devices and must only be worn under the prescription, direction and supervision of an eye care professional. The eye care professional needs to determine whether these lenses are appropriate for the individual patient and needs to ensure proper fit on the patient's individual eyes.

8. ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- 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 THEIR LENSES.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, **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 both lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE 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 **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONER.** The patient should bring their lenses, solutions and lens case with them to their eye care provider for culturing in order to better establish the identity of any organism associated with the patient's infection.

9. FITTING

Conventional methods of fitting contact lenses apply to the Horien Monthly Color Contact Lens. For a detailed description of the fitting techniques, refer to the "Fitting Procedure" section: in the Professional Fitting and Information Guide, copies of which are available from:

YUNG SHENG OPTICAL CO., LTD
No.8, Keya 2nd Road, Daya District, Taichung 42881, Taiwan

10. LENS REPLACEMENT / WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to over-wear the lenses 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.

Studies have not been conducted to show that **Horien Monthly Color Contact Lens** is 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 of non-lens wear per 24 hour period.

The lenses could be used maximum 30 days, then should be discarded afterwards.

Horien Monthly Color Contact Lens is indicated for daily wear. The maximum suggested wearing time for the lens is:

Day	Hours
1	4
2	6
3	8
4	10
5	12
6 and after-	all waking hours

11. LENS CARE DIRECTIONS

I. Soaking and Storing Your Lenses

Instruction for Use:

- Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

WARNING:

- Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.

II. Rub and Rinse Time

Instruction for Use:

- Rub and rinse your lenses for 10 seconds or more and then repeat with the second side for a total of 20 seconds.
- Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect your lenses and reduce the risk of contact lens infection.

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

III. Lens Case Care

Instruction for Use:

- Empty and clean your contact lens case with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner after each use. Never use water.
- Rinse the case with fresh, sterile disinfecting solutions (never use water).
- Wipe the lens case dry with fresh, clean, lint-free tissue.
- If you are air-drying your case, be sure that no residual solution remains in the case before allowing it to air dry. Never recap the lens case lids after use unless additional cleaning methods have been performed.
- Replace your lens case at least once every 3 months. Contact lens cases can be a source of bacterial growth.

WARNING:

- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

IV. Water Activity

Instruction for Use:

- Do not expose your contact lenses to water while you are wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness you're your lenses have been submersed in water such as when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

V. Discard Date (for care products)

Instruction for Use:

- Discard any remaining solution 3 months after opening.

WARNING:

- Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

12. CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning** and rinsing, to **disinfect**, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before** wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **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 saline solution prior to placement in the eye should reduce the potential for irritation.

13. CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

14. CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 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 more than 5 minutes, the patient should immediately consult the eye care practitioner.

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

16. HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the color, base curve, diameter, dioptic power, manufacturing lot number and expiration date of the lens.

DO NOT USE IF THE BLISTER PACK IS BROKEN OR THE SEAL HAS BEEN DAMAGED

17. REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing any contact lens or experienced with the lenses should be reported to:

YUNG SHENG OPTICAL CO., LTD
Address: No.8, Keya 2nd Road, Daya District, Taichung 42881, Taiwan