Contact Lens Company, Inc.

Horizon™ Contact Lens Package Insert

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. Additional copies can be obtained by calling Westcon Customer Service at 1-800-346-4303, or downloading a copy from Westcon's website at www.westconlens.com.

Vial Label Symbols Definition:


: Attention, consult the accompanying documentation


: Expiry Date

: Horizon™ UV Lens

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

: Sterile

B.C. : Base Curve
Dia : Diameter
Sph : Spherical power
Cyl : Cylinder power
SN : Serial/Barcode Number

PRODUCT DESCRIPTION

Horizon™ lenses are designed with varying base curves that conform to the shape of the radius of the cornea and center over the apex of the cornea to provide correction. Each lens provides corrective power, which corresponds to the refractive power of the eye being treated. Each Horizon™ contact lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens, generally of a diameter greater than 6.0 mm. The primary and secondary curves, as well as beveled edge configurations, are built into the lens for the purpose of aiding lens centration and comfort.

The color-enhanced lenses are available in shades of the following: blue, green, brown and aqua. Combining one or more reactive color additives with distilled water forms the color enhancement. The reactive color additives that may be used either alone or in combination are: Reactive Blue 19, Reactive Black 5, Reactive Red 11, Reactive Orange 78, Reactive Yellow 15, and Reactive Red 180. The action of the color-enhanced lens remains the same as the clear version; the color-enhancement changes the appearance of the lens by affixing a listed reactive color additive on that portion of the front surface of the lens that corresponds to the iris.

Horizon™ Contact Lenses must be chemically (NOT heat) disinfected.

MATERIAL DESCRIPTION

Horizon™ 55 The Horizon™ 55 lens material is methafilcon A. The lens consists of 45% methafilcon and 55% water by weight when immersed in buffered saline solution. The Horizon™ 55 (UV) contains BHPEA UV Absorber. The UV-absorber is included during the manufacturing process as a monomer. *

Lens Parameters

Diameter	10.0 mm to 24.0 mm
Base Curve	6.0 mm to 11.0 mm
Center Thickness	
Low minus:	0.06 mm to 0.15 mm
Plus:	0.14 mm to 0.70 mm
Powers	Unlimited power range
Bifocal Add Zone	1.8 to 4.0
Toric	
Axis:	0° to 180
Cylinder Power:	– 0.50 to –20.00
Physical/optical properties	
Specific Gravity	1.09
Refractive Index	1.411
Light Transmittance (tinted)	> 70%
Water Content	55%
Oxygen Permeability (Dk) **	

$$18.83 \times 10^{-11} \frac{(cm^2/sec)\ (ml\ O_2/ml \times mmHg)}{}$$

Horizon™ 59 The Horizon™ 59 lens material is hioxifilcon A. The lens material consists of 41% hioxifilcon and 59% water by weight when immersed in buffered saline solution. *

Lens Parameters

Diameter	10.0 mm to 15.0 mm
Base Curve	6.0 mm to 11.0 mm
Center Thickness	
Low minus:	0.06 mm to 0.15 mm
Plus:	0.14 mm to 0.60 mm
Powers	Unlimited power range
Bifocal Add Zone	1.8 to 4.0
Toric	
Axis:	0° to 180°
Cylinder Power:	– 0.50 to –10.00
Physical/optical properties	
Refractive Index	1.401
Light Transmittance (tinted)	> 70%
Water Content	59%
Oxygen Permeability (Dk) **	

$$24.0 \times 10^{-11} \frac{(cm^2/sec)\ (ml\ O_2/ml \times mmHg)}{}$$

Horizon™ 38 The Horizon™ 38 lens material is polymacon. The lens consists of 62% polymacon and 38% water by weight when immersed in buffered saline solution. *

Lens Parameters

Diameter	10.0 mm to 15.0 mm
Base Curve	6.0 mm to 11.0 mm
Center Thickness	
Low minus:	0.06 mm to 0.15 mm
Plus:	0.14 mm to 0.60 mm
Powers	unlimited power range
Toric	
Axis:	0° to 180°
Cylinder Power:	– 0.50 to –10.00
Physical/optical properties	
Specific Gravity	1.301
Refractive Index	1.44
Light Transmittance (tinted)	> 70%
Water Content	38%
Oxygen Permeability (Dk) **	

$$9.0 \times 10^{-11} \frac{(cm^2/sec)\ (ml\ O_2/ml \times mmHg)}{}$$

* When tinting Horizon™55, Horizon™ 59 or Horizon™ 38 lenses blue to make them easier to see when handling, copper phthalocyanine is added.
** At 35°C, Fatt method.

ACTIONS

When placed on the human cornea in its hydrated state, the Horizon™ contact lens acts as a corrective refracting medium to focus light rays from near and distant objects on the retina. The toric lens design provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus the light rays on the retina.

INDICATIONS
(reasons to use)

Horizon™ contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic or not-aphakic persons with non-diseased eyes. The color-enhanced version is indicated for daily wear to enhance or alter the apparent eye color.

CONTRAINDICATIONS
(reasons not to use)

DO NOT USE the Horizon™ 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 that is to be used to care for the Horizon™ 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.

WARNINGS

Advise patients of the following warnings relating to contact lens wear:

- Problems with contact lenses 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 lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The patient should be advised to immediately remove their contact lenses and promptly contact their eye care practitioner if they experience eye discomfort, excessive tearing, vision changes, or redness of the eye. .
- All contact lens wearers must see their eye care practitioner as directed.
- Daily wear lenses are **not** indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

PRECAUTIONS

Special Precautions for eye care practitioner:

- Clinical studies have demonstrated that Horizon™ contact lenses are 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, material 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.
- Aphakic patients should not be fitted with Horizon™ 59 (hioxifilcon A) until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb 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 lenses to absorb residual fluorescein irreversibly.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following precautions for care and safety:

Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the Patient Instructions for the Horizon™ Contact Lenses and those prescribed by the eye care practitioner.

Contact lens solutions:

- Always use FRESH, STERILE, UNEXPIRED lens care solutions.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses.
- Never use solutions recommended for conventional hard contact lenses only.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.

Lens care systems:

- Only chemical (NOT heat) lens care systems can be utilized for the Horizon™ contact lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying will damage the lenses. Should a lens dry out, follow these directions for **Care for a Dried Out (Dehydrated) Lens:**
  - Handle the lens carefully. If the lens is adhering to a surface, apply sterile saline before handling.
  - Place the lens in the storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour, until it returns to a soft state.
  - Before wearing, clean and disinfect the re-hydrated lens, using the recommended lens care system.
  - If, after soaking, the lens does not become soft or the surface of the lens remains dry, DO NOT PUT THE LENS ON THE EYE. Do not use the lens unless it has been examined by the eye care practitioner.

Handling:

- Always wash and rinse and dry 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-based cosmetics are less likely to damage lenses than oil-based.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container, unless it is a tool specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.

Wear:

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- 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.
- The lens should move freely on the eye for the continued health of the eye. If the lens sticks (stops moving) on the eye, follow these directions for **Care for a Sticking (Non-moving) Lens:**
  - Apply a few 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, IMMEDIATELY consult the eye care practitioner

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 completed to show that the Horizon™ contact lenses are safe to wear during sleep.

The Horizon™ contact lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

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

ADVERSE REACTIONS

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

- Eyes stinging, burning, itching (irritation), or other eye pains.
- 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 the discomfort or problem stops, then look closely at the lens. If the lens has 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 lenses, then reinsert it. After reinsertion, if the problem continues, the patient should IMMEDIATELY REMOVE THE LENS 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 be instructed to keep the lens off the eye, and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

GENERAL LENS CARE

- Always wash, rinse and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses.
- Do not put lenses in the mouth.
- Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Always use FRESH, STERILE, UNEXPIRED lens care solutions.
- 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.
- 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.
- Use a recommended system of lens care, and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses.
- Disinfecting is necessary to destroy harmful germs.
- Disinfection of the Horizon™ contact lenses by a chemical (NOT heat) lens care system is necessary to remove potentially harmful microorganisms.

BASIC INSTRUCTIONS:

Cleaning

- Clean one lens first (always the same lens first to avoid mix-ups), then rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Put lens into the correct chamber of the lens storage case which has been filled with the appropriate solution. Repeat the procedure for the second lens.

Chemical Disinfecting

- Your eye care practitioner should recommend a lens care system that is appropriate for your Horizon™ contact lens. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.
- The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.
- Horizon™ contact lenses must be chemically disinfected; they cannot be heat (thermally) disinfected
- 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 on the eye should reduce the potential for irritation.

Storing Lenses:

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are 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 lenses.

BASIC INSTRUCTIONS: (continued)

Lens Case Care:

- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens manufacturer, and then allow the lens case to air dry. When the case is used again, refill it with fresh solution. Replace lens case according to manufacturer or eye care practitioner instructions.

FITTING

Conventional methods of fitting contact lenses apply to the Horizon™ contact lenses. For a detailed description of the fitting techniques, refer to the Horizon™ Contact Lenses Professional Fitting and Information Guide, copies of which can be downloaded from Westcon's website at www.westconlens.com, or requested from:

WESTCON CONTACT LENS COMPANY, Inc.
611 Eisenhauer St.
Grand Junction, CO 81505
(800) 346-4303

HOW HORIZON™ CONTACT LENSES ARE SUPPLIED

Each lens is supplied sterile in a glass vial containing sterile normal saline solution USP, buffered with sodium bicarbonate USP. The vial label identifies the base curve, diameter, diopter power, serial/barcode number, color and expiration date of the lens. In the event of damage to the sterile packaging (vial or cap), do not use. Contact Westcon for their return policy.

LIGHT TRANSMITTANCE CHARACTERISTICS

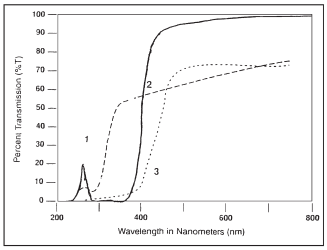

Fig. 1

Figure 1 illustrates the transmittance of a typical Horizon™ UV lens, a human cornea and human lens.

Curve 1 represents the transmittance of a 0.1 mm nominal center thickness Horizon™ UV lens.

A small transmittance peak appears in the Curve 1 in the 200-290 nm ranges. The transmittance across the waveband is 0-20%. This peak is located in the waveband of ultraviolet radiation (200-290 nm) that is absorbed by the earth's atmosphere.

Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24 year old person and a human lens from a 25 year old person, respectively.

ULTRAVIOLET (UV) ABSORBING HORIZON™ PRODUCTS ADDITIONAL PACKAGE INSERT INFORMATION

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Horizon™ Contact Lenses should be reported to:

WESTCON CONTACT LENS COMPANY, Inc.
611 Eisenhauer St.
Grand Junction, CO 81505
800-346-4303

To report serious adverse experiences and adverse reactions in patients who are in the European Union, please see the additional package insert regarding Westcon's European Union Authorized Representative.

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

Westcon Contact Lens Co.
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