

## **Horizon™ Products Package Insert**

Horizon 38 (polymacon), Horizon 38 (polymacon) Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon) Soft Hydrophilic Contact Lens for Daily Wear  
(Hereinafter referred to as “Horizon 38 (polymacon) 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 the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

### **Description:**

Horizon 38 (polymacon)

The Horizon 38 (polymacon) Contact 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 to which it is being treated.

Each Horizon 38 (polymacon) 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 mm. The primary and secondary curves as well as beveled edge configurations are built into the lens for the purpose of aiding on the lens centration and comfort.

The Horizon Enhanced lenses are available in shades of the following: blue, green, brown and aqua.

When color enhancement has been added to the lens, the lens may be disinfected using chemical systems only.

Either a heat or chemical care systems can disinfect Horizon 38 (polymacon) Contact Lenses that are not color enhanced.

The Horizon 38 (polymacon) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	10.0 mm to 24.0mm
Base Curve:	6mm to 11.0 mm
Center Thickness:	Low Minus Lens-.06mm to .15mm Plus Lens-.14 to .60
Powers:	unlimited power range
Toric	Axis- 0° to 180° Power- -.50 to -10.00

The physical/optical properties of the lens:

Specific Gravity: 1.301

Refractive Index: 1.44

Light Transmittance: Tinted Version > 70%  
Clear Version >95%

Water Content: 38%

Oxygen Permeability  $D_k = 9 \times 10^{-11}$  (cm<sup>2</sup>/sec) ml O<sub>2</sub>/ml x mmHg at 25°C.

Note: Oxygen Permeability measured by Schema Versatae model 920 connected to a polarographic cell.

### **Actions**

When placed on the human cornea in its hydrated state, the Horizon 38 (polymacon) Contact Lens acts as a corrective refracting medium to focus light rays from near and distant objects on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus the light rays on the retina.

### **Indications**

The Horizon 38 (polymacon) , Horizon 38 (polymacon) Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon) are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic, astigmatism) in aphakic or not-aphakic persons with nondiseased eyes.

The color-enhanced version is indicated for daily wear to enhance or alter the apparent eye color. The color-enhanced lenses can be chemically disinfected only. The clear lenses may be disinfected using a heat o chemical disinfecting system.

### **CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE the Horizon 38 (polymacon) 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, conjunctive, 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 38 (polymacon) 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:

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**; therefore, if you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **immediately remove your lenses** and promptly contact your eye care practitioner.

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 contact lenses manufactured from polymacon 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 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 38 (polymacon) Contact Lens 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 care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses 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 either a heat or chemical care systems can be utilized for the Horizon 38 (polymacon) contact lenses manufactured from the polymacon material. **CAUTION: DO NOT MIX OR ALTERNATE HEAT (thermal) AND CHEMICAL (not heat) LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.** 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 wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. 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 nonmovement 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 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.
- 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.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the Patient instructions for the Horizon 38 (polymacon) Contact Lens and those prescribed by the eye care practitioner.
- 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.
- Always handle lenses carefully and avoid dropping them.
- 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.
- 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.
- 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 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) or 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 LENSES.**
- If discomfort or problems 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 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 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 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 lenses do apply to the Horizon 38 (polymacon) Contact Lenses. For a detailed description of the fitting techniques, refer to the Horizon 38 (polymacon) Professional Fitting and Information Guides, copies of which are available from:

WESTCON CONTACT LENS COMPANY, Inc.  
611 Eisenhauer St.

Grand Junction, CO 81505  
1 (800) 346-4303

## 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. The Horizon 38 (polymacon) Contact Lenses are indicated for daily wear. The maximum suggested wearing time for these lenses 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 THE HORIZON 38 (POLYMACON) CONTACT LENS IS SAFE TO WEAR DURING SLEEP.**

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

### Basic Instructions:

Care of contact lenses takes very little time and involves TWO essential steps - **CLEANING AND DISINFECTION**. 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 lenses. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Disinfection of the contact lens is necessary to remove potentially harmful microorganisms. Use 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. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING**. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses 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 lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.

**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.

**Note:** The eyecare practitioner should recommend a care system that is appropriate for the Horizon 38 (polymacon) Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

**Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the 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** lenses using the system recommended by the eye care practitioner.
- To store lens, 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.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens manufacturer; 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 manufacturer or your eye care practitioner.
- 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.
- Either a heat or chemical care systems can disinfect Horizon 38 (polymacon) Contact Lenses. When color enhancement has been added to the lens, the lens may be disinfected using chemical systems only.

### **Chemical Disinfection:**

- Your eye care practitioner should recommend a care system that is appropriate for your Horizon 38 (polymacon) Contact Lens. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.
  - Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**
  - 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.

### **Heat (Thermal) Lens Disinfection**

- Your eye care practitioner should recommend a care system that is appropriate for your Horizon 38 (polymacon) Contact Lens. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.
- When color enhancement has been added to the lens, the lens may be disinfected using chemical systems only.

### **HOW SUPPLIED:**

Each lens is supplied sterile in a glass vial containing sterile normal saline solution USP, buffered with sodium bicarbonate USP. The glass vial is marked with the base curve, diameter, diopter power, manufacturing lot number, color and expiration date of the lens.

**REPORTING OF ADVERSE REACTIONS:**

All serious adverse experiences and adverse reactions observed in patients wearing the contact lens should be reported to:

WESTCON CONTACT LENS COMPANY, Inc.  
611 Eisenhower St.  
Grand Junction, CO 81505  
1-800-346-4303

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

Date: 1/04