DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Tinted)

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 lenses.

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

DESCRIPTION

The DESIO soft contact lenses are available as spheric or toric lens designs. The nonionic lens material, (polymacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in saline solution.

DESIO lenses are available clear or tinted to enhance or alter the apparent color of the eye. Lenses are tinted with one or a combination of one or more of the following ‘listed’ color additives:

<table>
<thead>
<tr>
<th>Name of Colorant</th>
<th>Listing</th>
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<tbody>
<tr>
<td>D&amp;C Yellow 10</td>
<td>21 CFR § 74.3710</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>21 CFR § 73.3126</td>
</tr>
<tr>
<td>Iron Oxide (Red)</td>
<td>21 CFR § 73.3125</td>
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<tr>
<td>[Phthalocyaninato(2-)] Copper</td>
<td>21 CFR § 74.3045</td>
</tr>
<tr>
<td>Phthalocyanine Green</td>
<td>21 CFR § 73.3124</td>
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<tr>
<td>Carbazole Violet</td>
<td>21 CFR § 73.3107</td>
</tr>
<tr>
<td>Reactive Blue 19</td>
<td>21 CFR § 73.3127</td>
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<tr>
<td>C.I. Reactive black 5</td>
<td>21 CFR § 73.3127</td>
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The physical properties of the lens are:

- **Refractive Index**: 1.43
- **Light Transmission (clear)**: greater than 96%
- **Light Transmission (tinted)**: greater than 96%
  - (corresponding to pupil)
  - Opaque or 0-10%
    - (corresponding to iris)
- **Surface Character**: hydrophilic
- **Water Content**: 38±2%
- **Specific Gravity**: 1.17 (hydrated)
- **Oxygen Permeability**: 12.48 x 10^{-11} (cm^2/sec)(mLO_2)/(ml x mmHg @ 35°C)

The lenses are manufactured in spherical and toric configurations with the following features and properties:

- **Chord Diameter**: 14.00 mm to 15.00 mm
- **Center Thickness**: 0.050 mm to 0.210 mm
- **Base Curve**: 8.0 mm to 8.7 mm
- **Power Range**
  - Cast-molded: -10.00D to +10.00D in 0.25D steps
  - Lathe-cut: -20.00D to -10.00D & +20.00D to +10.00D in 0.25D steps
- **Cylinder Power**: -0.25D to -3.00D in 0.25D steps
- **Cylinder Axis**: 10° to 180° in 10° steps

ACTIONS

In its hydrated state, the DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS

The DESIO (polymacon) Spherical Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.
The DESIO (polymacon) Toric Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4.00 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

NOTE: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the DESIO (polymacon) Spherical and Toric Daily Wear 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 for the DESIO (polymacon) 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.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

- Patients wearing lenses on a frequent/planned replacement schedule should not reuse or “top off” old solution left in the 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 the case.
- When disinfecting frequent/planned replacement lenses the patient should rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections (see the frequent/planned replacement wearer’s instruction guide for detailed instructions).
- The patient should never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.
- Patients should not store their lenses or rinse their lens case with water or any non-sterile solution. Patients wearing frequent/planned replacement lenses must only use fresh multi-purpose solution (or sterile saline solution) so their lenses or lens case are not contaminated. Use of non-sterile solution can lead to severe infection, vision loss or blindness.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the patient’s lenses have been submersed in water such as when swimming in pools, lakes, or oceans the patient should discard them and replace them with a new pair. Patients should be instructed to ask their eye care practitioner (professional) for recommendations about wearing their lenses during any activity involving water.
- Using the multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- Multi-purpose solution is not to be used with Daily Disposable lenses at any time.

All contact lens wearers must see their eyecare practitioner as directed.
PRECAUTIONS

Special Precautions for the Eyecare Practitioner:

- Clinical studies have demonstrated that contact lens manufactured from (polymacon) are safe and effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of lenses, 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 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 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 eyecare practitioner.
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens 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 lens to absorb residual Fluorescein irreversibly.
- Before leaving the eyecare 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.
- Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.

PRECAUTIONS FOR DAILY DISPOSABLE WEAR

- If the lenses are prescribed for disposable wear. They are to be disposed of once they are removed from the patient’s eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Carefully follow the handling, insertion, removal, emergency care instructions in the daily disposable patient instructions for the DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lens and those prescribed by the eyecare practitioner.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT WEAR

- Different solutions cannot always be used together, and not all solutions are safe for use with all lens. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens 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 solutions. 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 rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the frequent/planned replacement patient instructions for the DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lens and those prescribed by the eyecare practitioner.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT AND DISPOSABLE WEAR

- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving 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 eyecare practitioner.
- 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.
- Never wear lens beyond the period recommended by the eyecare practitioner.
- Water activity: The Patient should not expose their contact lenses to water while wearing them.
- 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 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.
- Discard lens if wearing daily disposable.
- For frequent/planned replacement wearers: if discomfort or problem(s) 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 eyecare 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 do and do not apply to the DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lens. For a detailed description of the fitting techniques, refer to DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lens Professional Fitting and Information Guide, copies of which are available from:

QUALIMED SRL
PIAZZA DELLA RADIO 37
00146 ROMA
ITALY
Phone# +39 0331 162 9910
www.desioeyes.it

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to over wear the lens initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The DESIO (polymacon) Soft Contact Lens are indicated for daily wear. The maximum suggested wearing time for this lens is:

<table>
<thead>
<tr>
<th>DAY</th>
<th>HOURS</th>
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<tr>
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<td>6</td>
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<td>2</td>
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<td>12</td>
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<td>5</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>All Waking hours *</td>
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</table>
STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT DESIO (polymacon) Spherical and Toric Daily Wear Soft Contact Lens IS SAFE TO WEAR DURING SLEEP.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

LENS CARE DIRECTIONS

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend procedures and products for each individual patient in accordance with their particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient.

Disposable Wear: This section, LENS CARE DIRECTIONS, is not applicable to Daily Disposable lenses. For complete information and instruction concerning Daily Disposable lenses refer to the DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses (Tinted) Daily Disposable Patient Instruction/Wearer’s Guide.

Frequent/Planned Replacement: Eyecare 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:

Basic Instructions: Care of contact lens takes very little time and involves THREE essential steps – CLEANING, RINSING AND DISINFECTING. 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 lens. Always use FRESH, STERILE UNEXPIRED lens care solutions. Use the recommended chemical (not heat) lens care system. 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 lens. Do not put lens in the mouth. Lens 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 lens. Eyecare practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lens while they are being worn to make them more comfortable.

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.

Specific Instructions for Use and Warnings:

a. Soaking and Storing the Lenses

Instruction for Use:
- Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).
- WARNING: Do not reuse or “top off” old solution left in the 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 in the case.

b. Rub and Rinse Time

Instruction for Use:
- Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution to adequately disinfect the lenses.
- WARNING: Rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

C. Lens Case Care

Instruction for Use:
- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace the lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.
WARNING:
- Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to prevent contaminating the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. Water Activity
Instruction for Use:
- Do not expose the contact lenses to water while wearing them.

WARNING:
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. The patient should ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

e. Discard Date on Multipurpose Solution Bottle
Instruction for Use:
- Discard any remaining solution after the recommended time period indicated on the bottle of multipurpose solution used for disinfecting and soaking the contact lenses.
- The Discard date refers to the time the patient can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:
- Using the multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

Lens cleaning, disinfection, and storage:
Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing 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 lens using the system recommended by the manufacture and/or the eyecare practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens is not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lens.

Rinsing
Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing or multipurpose solution.

Lens Care Regimen:
Patients must adhere to the lens care regimen recommended by their eyecare practitioner for the DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses. Failure to follow this procedure may result in development of serious ocular infections.

Care for a dried out (dehydrated) dry lens:
If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 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 nonmovement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eyecare practitioner.

Care for a sticking (non-moving) lens:
The DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lens must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, it should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfection cycle.

Lenses prescribed for frequent replacement:
It is recommended that the DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lens be discarded and replaced with a new lens every three (3) months. However, as the Eyecare practitioner, your are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

CHEMICAL (NOT HEAT) LENS DISINFECTION:
1. Wash and rinse hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. Rub and rinse the lenses for 15-20 seconds or more and then repeat with the second side for a total of 2 times 30 seconds or more. Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect the lenses and reduce the risk of contact lens infection.
3. After cleaning, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.

4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

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 rinsing solution prior to placement on the eye should reduce the potential for irritation.

- When using hydrogen peroxide lens care systems, the patient must use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution. Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Eye Redness
- Or Other Eye Problems

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

- 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.

For additional information concerning the care, cleaning and disinfecting of contact lenses refer to the DESIO (polymacon) Daily Wear Soft (hydrophilic) Contact Lens Patient Instruction/Wearer’s Instruction Guide.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of the patient's lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

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:

The DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses are supplied sterile in sealed blister packages containing saline solution with preservative Polyhexamethylene Biguanide (PHMB). The base of the package is made from polypropylene, which is covered with a laminated foil seal on top.

The blister packages are marked with the base curve, diameter, dioptric power, toric cylinder power, toric cylinder axis, lens color, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing **DESIO (polymacon) Spherical and Toric Daily Wear Soft (hydrophilic) Contact Lenses** or experienced with the lens should be reported to:

**QUALIMED SRL**  
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00146 ROMA  
ITALY  
Phone# +39 0331 1629910  
www.desioeyes.it