**SOFLENS® (polymacon) Contact Lenses**

**DESCRIPTION**

Extended wear lenses are not indicated for overnight wear, and should not be used under reduced illumination conditions such as night driving. Clinical studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

Extended wear lenses are indicated for extended wear from 1 to 7 days between removals, beginning with a proper care regimen. Some practitioners may prescribe disposable wearing periods from 1 to 7 days with specified intervals of no lens wear for consecutive days that the lenses are worn between removals, beginning with the continuing ocular health of the patient and lens performance on eye should be obtained satisfactory visual acuity, in a power range of –9.00 to +15.00 diopters. These contact lenses are indicated for the correction of visual acuity of myopic and hyperopic, phakic patients. Patient Information Booklet with the patient at the time of the initial examination.

**INDICATIONS (USES)**

- **Daily Wear**
  - The Bausch + Lomb SOFLENS® (polymacon) Contact Lenses are indicated for the correction of refractive astigmatism (myopia and hyperopia) in aphakic and/or pseudophakic patients with non-diseased eyes, that exhibit astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity, in a power range of –20.00 to +20.00 diopters.

- **Extended Wear**
  - The Bausch + Lomb SOFLENS® (polymacon) Contact Lenses are indicated for extended wear from 1 to 7 days between removals, beginning with a proper care regimen. Some practitioners may prescribe disposable wearing periods from 1 to 7 days with specified intervals of no lens wear for consecutive days that the lenses are worn between removals, beginning with a consistent ocular health of the patient and lens performance on eye should be obtained satisfactory visual acuity, in a power range of –9.00 to +15.00 diopters. These contact lenses are indicated for the correction of visual acuity of myopic and hyperopic, phakic patients. Patient Information Booklet with the patient at the time of the initial examination.

**CONTRAINDICATIONS (REASONS NOT TO USE)**

- **DO NOT use the Bausch + Lomb SOFLENS® (polymacon) Contact Lenses 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 eye)
  - Corneal hypoxia (reduced corneal sensitivity), in anophthalmic
  - Any systemic disease that may affect the eye be exacerbated by wearing contact lenses
  - Allergic reactions of ocular surfaces or adverse (contact) skin reactions that may be induced or exacerbated by wearing contact lenses or contact lens solutions
  - Allergic conjunctivitis or contact dermatitis
  - Any active corneal infection (bacterial, fungal, or viral)
  - If eyes become red or irritated

**WARNINGS**

- Patients should be advised of the following warnings pertaining to contact lens use:
  - Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow the eye care practitioner’s direction and adhering to the instruction is essential for the 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.
  - Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear these lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight.
  - Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
  - NaturalSoft® Contact Lenses reduce the amount of light entering the eye and should not be used under reduced illumination conditions such as night driving.
  - As with all soft contact lenses, Occasions™ Multifocal and PA 1 Multi-Contact lenses may require a number of fitting procedures before a final lens selection is made. As a patient’s add requirement increases, the probability of the patient achieving good visual acuity decreases. A realistic visual expectation for the average patient is that distance VA will be comparable to spectacles; near VA probably slightly less.

**IMPORTANCE**

This package insert replaces the previous edition, and superseded all prior inserts for the products described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, and should not be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient prescribed lens.

**CAUTION**


**VISION CORRECTION USE**

For all Bausch + Lomb SOFLENS® (polymacon) Contact Lenses (including clear, visibility tinted, cosmetically tinted, daily wear or extended wear polymacon hydrogel contact lenses).

SOFLENS includes the following types:
- O3, O4, Occasions™ Multifocal, Optimas™ 38, Optimas™ 38/3P, L3, U4, Soflens™, H103, HO4, B3, BA, PAF, F3, H4, N4, and NaturalSoft™ Contact Lenses.

Spherical Lenses for:
- Neovisiontint (Mysia), Freshnessight (Hyperopia), Presbyopia, Tint-aphakic and/or after Cataract Surgery (Aphakia)

**PACKAGE INSERT / FITTING GUIDE**

**SOFLENS® (polymacon) Contact Lenses**

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**APPLICATIONS**

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  - Any active corneal infection (bacterial, fungal, or viral)
  - If eyes become red or irritated

**WARNINGS**

- Patients should be advised of the following warnings pertaining to contact lens use:
  - Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow the eye care practitioner’s direction and adhering to the instruction is essential for the 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.
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### PRECAUTIONS

#### Precautions for Eye Care Professionals
- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive power designs, 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 professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettable, central and peripheral thickness, and optic zone diameter.
- The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for portions of the power range, including plus powers and some power designs. For the clinical study, the rate of refractive keratometry was found to be higher with higher lens powers (see Clinical Study section on keratometry).
- 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 continuation of lens wear is recommended for the patient and lens performance on eye should be carefully monitored by the prescribing eye care professional.
- Eye care professionals should REMOVIE A LENS IMMEDIATELY if any eyes become irritable or red.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses should be placed on the cornea and left in place for 30 minutes. Fluorescein is used in the eyes, the eyes should be flushed with sterile saline solution that is recommended for eye care professionals.
- The patient should be instructed to always discard disposable lenses and lenses worn on a planned replacement schedule after the recommended number of weeks as recommended by the eye care professional.
- Some patients will not be able to tolerate continuous wear even if it is able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eye care professional should conduct early and frequent follow-up examination to determine ocular response to continuous wear.
- As with any contact lens, follow-up visits are necessary to assure the continued health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Equate™ Monthly Toric Contact Lenses until the determination is made that the eye has healed completely.

#### SELECTION OF PATIENTS
- The eye care professional should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Equate™ Monthly toric Patient Information Booklet available from Walmart and understand its contents prior to dispensing the lenses.
- **Handling Precautions**
  - Always wash and rinse hands before handling lenses. Do not get lotions, lotions, creams, disinfectants, or soap into 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 fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or irritation.
  - Always handle lenses carefully and avoid dropping them.
  - Do not touch the lenses with fingernails.
  - Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions provided by the Patient Information Booklet for the Equate™ Monthly Toric Contact Lenses and these prescribed by the eye care professional.
  - Never use tweezers or other tools to remove lenses from the lenses container unless specifically indicated for that use. Pour the lens into the hand.
- **Solution Precautions**
  - Do not use the Allergan Ultraspec Disinfecting System or any of its components (Ultraspec Disinfecting Solution, Ultraspec Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme Enzymatic Cleaner) to clean and disinfect the Equate™ Monthly Toric Contact Lenses because the lens dimensions will be altered.
  - Eye injury due to infection or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeling instructions with the patient.
  - Always use fresh unopened lens care solutions.
  - Always follow directions in the package inserts for the use of contact lens solutions.
  - sterilize unreserved solutions, when used, should be discarded after the time specified in the labeling directions.

#### ADVERSE REACTIONS
- The patient should be informed that the following problems may occur:
  - Eye sting, burn, or itching (irritation), or other eye pain
  - Comfort is less than when lens was first placed on eye
  - Abrasion/lesion of thin corneal epithelium (abrasion, erosion, scraping)
  - Excessive tearing (watery eye)
  - Unusual eye sensations
  - Redness of the eyes
  - Redness/sharpened vision (poor vision acuity)
  - Blue-stain, xerophthalmia, or halos around objects
  - Sensitivity to light (photophobia)
  - Dry eyes

- In the patient notices any of the above, he or she should be instructed to:
  - Immediately remove lenses.
  - If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care professional (by phone or in person) for directions on how to remove the lens safely, or what to do for in-eye use.
  - If the discomfort continues, the patient should immediately call their eye care professional for care.

#### Important Treatment Information for Adverse Reactions
- **Right-threatening ocular complications** that require immediate care can develop rapidly, and therefore early recognition and treatment of problems are critical. Derangement of the corneal epithelium is one of the most serious potential consequences, and may be ambiguous in its early stages. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.
- Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency and treated by eye care professional familiar with normal keratometry and without any of these conditions.
- The lens should be removed as soon as possible. Standard therapy for corneal abrasions such as eye patching or the use of sterile saline solution, with or without an antibiotic ointment may exacerbate the condition.
- If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately.
- The eye care professional should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Equate™ Monthly toric Patient Information Booklet available from Walmart and understand its contents prior to dispensing the lenses.

#### Handling Precautions
- Always wash and rinse hands before handling lenses. Do not get lotions, lotions, creams, disinfectants, or soap onto 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 irritation.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lenses with fingernails.
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  - Eye injury due to infection or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer’s labeling instructions with the patient.
  - Always use fresh unopened lens care solutions.
  - Always follow directions in the package inserts for the use of contact lens solutions.
  - Sterile unreserved solutions, when used, should be discarded after the time specified in the labeling directions.

#### Lens Wearing Precautions
- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stays moving) on the eye, the eye should be rinsed with sterile saline solution, and then covered with a fresh contact lens.
- Sticking lenses should move freely on the eye for the continued health of the eye. If movement of the lenses continues, the patient should be instructed to immediately consult his or her eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

#### Lens Care Precautions
- Contact lenses can be a source of bacterial growth. To prevent contamination and/or help avoid serious eye injury, always érinse and rinse the lenses case with fresh, sterile rinsing solution and allow to dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

#### FITTING PROCEDURE

### 1. Pre-Fitting Examination
- A pre-fitting patient history and examination are necessary to:
  - determine whether a patient is a suitable candidate for contact lenses (general health and mental and physical state).
  - make ocular measurements for initial contact lens parameter selection, and
  - collect and record baseline clinical information to which post-fitting examination can be compared.
- A prefitting examination should include spherical/plano refraction and VA, keratometry, and binocular simultaneous examination.

### 2. Initial Lens Power Selection
- Select lenses most closely matches that of the patient.
- Place the lens on the eye and allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the toric character of the contact lense, and individual tear composition may cause slight changes in fitting characteristics.
- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

### 3. Initial Lens Evaluation
- To determine proper lens parameters, observe the lens relationship to the eye:
  - The toric diagnostic lenses is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction.
- Rotation evaluation: The center guide mark should be located at the inferior limbus. Once oriented, radial rocking should be limited to less than 7°.
- Movement: The lens should provide secure fitting while:
  - Primary gaze blink
  - Upope blink
  - Upope lag
  - Centration: The lens should provide full corneal coverage.
b. Determine contact lens power. When the toric diagnostic lens does not have adequate disinfect lenses and reduce the risk of contact lens infection.

Soaking and Storing Lenses

• Method 1 - Determine which eye will accept the added power with the least over-correction be prescribed.
• Method 2 - Determine which eye will accept the added power with the least over-correction be prescribed.

With your finger, gently rotate the lens approximately 45° to the temporal side. It may be differentiated from a properly fitted lens by having the patient gaze upward. A well-fitted lens will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 1.25mm while a steep lens will remain stable in relationship to the cornea, particularly with the blink.

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• If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and damaged lens.

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Therefore, the importance of adhering to a proper, initial wearing schedule should be stressed to these patients.

The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Extended Wear (Greater than 24 hours or while asleep):

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner’s experience and professional judgment. Bausch + Lomb recommends that extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the WARNINGS section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

b. Monovision Needs Assessment

The patient should be informed that if chemicals of any kind (household chemicals) are used on the contact lenses, the patient should not be used until the patient has returned to the office. The prescribed initial daily wear schedule should be adhere to.

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LENS CARE

Patient 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 appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient. For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Equate™ Monthly Toric (balafilcon A) Contact Lens Patient Information Booklet.

a. Soaking and Storing Lenses

Instruction for Use:
Use only fresh contact lens disinfecting solution each time you soak (store) lenses.

WARNING:
Do not reuse or “top off” old solution left in 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.

d. Rub and Rinse Time

Instruction for Use:
Following the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

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

c. Lens Care Care

Instruction for Use:
• 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. Air-drying, be sure that no residual solution remains in the case before allowing it to air dry.
• Replace lens case according to the directions given by your eye care professional or the labeling that came with your case.
• Contact lens cases can be a source of bacterial growth.

WARNING:
Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection; vision loss or blindness.

b. Water Activity

Instruction for Use:
Do not expose contact lenses to water while wearing them.

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

e. Discard Date on Solution Bottle

Instruction for Use:
Discard any disinfecting solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.

WARNING:
Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

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

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

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals.

CARE FOR A DRIED OUT (DEHYDRATED) OR DRY LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply saline before handling.

To rehydrate the lens:
• Handle the lens carefully.
• Placing the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least one hour until it returns to a soft state.
• Clean and disinfect the rehydrated lens using a recommended lens care system.
• If after soaking, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution.

PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to 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 THEN REMOVE LENSES PROMPTLY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each Bausch + Lomb SORLENS® (polyHEMA) Contact Lens is supplied in a plastic container or a glass package. The plastic container has a solution of phosphate buffered saline with 0.05% polyquaternium alcohol or a solution of borate buffered saline, while the glass vial has a 0.09% sodium chloride solution. The container is marked with the manufacturing lot number of the lens, the base curve, diameter and expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb SORLENS® (polyHEMA) Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609 USA

Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720