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**DESCRIPTION**

The Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is a soft hydrophilic contact lens which is available as a spherical lens. The lens is made from the polymacon material, a hydrophilic polymer of 2-hydroxyethyl methacrylate, and is 36.5% water by weight when immersed in a saline solution. This lens is tinted blue with approximately 90% of Reactive Blue 246. The physical / optical properties of the lens are:

- **Specific Gravity:** 1.12
- **Refractive Index:** 1.43
- **Light Transmittance**
  - CIE value—approximately 80% to 98%
- **Water Content:** 36.6%
- **Oxygen Permeability:** 8.4 x 10⁻⁹ cm³ (STP) x mm Hg / (sec x cm² x mm Hg) @ 34°C

**HOW THE LENS WORKS (ACTIONS)**

In its hydrated state, the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

- **Diameter:** 14.0mm
- **Center Thickness:** 0.035mm (0.250 to 0.600D)
- **0.03mm to 0.06mm (0.625 to 0.900D)
- **0.038mm to 0.024mm (0.050 to 0.020D)**

**CONTRAINDICATIONS (REASONS NOT TO USE)**

DONOT USE the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute or 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 tears (dry eyes)
- Corneal hypoplasia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exacerbated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercuric or thimerosal, in a solution which is to be used to care for the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
WARNINGS
After a thorough eye examination, including appropriate medical and background, patients should be fully apprised by the prescribing professional of all the risks with contact lens wear. Patients should be advised of the following potential warnings pertaining 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 professional’s direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including auto-inoculation, can develop rapidly and lead to loss of vision.

- When prescribed for Traditional or Frequent/Planned Replacement Wear, the need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be emphasized to the patient.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional.

Extended Wear
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some research suggests that these complications are caused by one or more of the following: a weakened corneal immunity to infections, particularly during a closed-eye condition, as a result of hypoxia, an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient, improper lens disinfection or cleaning by the patient; contamination of lens care products; proper need for the patient to avoid the possibility of the lens being worn for extended periods of time. When lenses are worn for extended periods, there is a risk of exposure to changes in the environment.

- While the great majority of patients successfully wear contact lenses, extended wear of lenses is also reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

- The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, eye care professionals should consider the patient’s tolerance for extended wear time before prescribing extended wear at all or partial extending wear times from occasional extended wear to extended wear over periods from 7 days with specified intervals of no lens wear for certain patients, follow-up visits, and with proper care regimen.

Solution Precautions
Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer’s labeled lens care instructions with the patient.

- Always use fresh unpreserved lens care solutions.

- Always follow directions in the package inserts for the use of contact lens solutions.

- Store unused solutions, when used, should be discarded according to the time specified in the labeling directions.

- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (dorm). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens storage surface does become dried out.

- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.

- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an Acanthamoeba keratitis infection.

- Never use conventional hard contact lens solutions that are not also recommended for use with preservatives.

- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.

- Do not heat the chemical disinfection solution or lenses.

Precautions
Precautions for Eye Care Professionals
- 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 eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optical characteristics, in determining the appropriate lens choice for each patient.

- 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 low minus powers. In the U.S. clinical study of the SofLens® (spherical) lens, the rate of infiltrative keratitis was found to be higher with higher minus powers.

- The potential impact of these factors on the patient’s ocular health should be carefully weighted against the needs for refractive correction; therefore, the prescribing eye care professional should carefully monitor the continuing ocular health of the patient and lens performance on eye.

- Patients who wear contact lenses, such as the Bausch + Lomb PureVision® for a Traditional or Frequent/Planned Replacement lens, to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- The SofLens® 38 (polymacon) Visibility Tinted Contact Lenses may be worn only on a Frequent / Planned Replacement schedule after the recommendation written wearing schedule prescribed by the eye care professional.

- When prescribed for a Traditional or Frequent/Planned Replacement lens in the Patient Information Booklet if lens surface does not dry when removed, immediately remove and store the lens container.

- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Always handle lenses carefully and avoid dropping them.

- Do not touch the lenses with fingernails.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb PureVision® for a Traditional or Frequent/Planned Replacement Contact Lens and those prescribed by the eye care professional.

- Never use any other tools or devices to retrieve lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Solution Precautions
Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer’s labeled lens care instructions with the patient.

- Always use fresh unpreserved lens care solutions.

- Always follow directions in the package inserts for the use of contact lens solutions.

- Store unused solutions, when used, should be discarded according to the time specified in the labeling directions.

- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (dorm). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens storage surface does become dried out.

- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.

- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an Acanthamoeba keratitis infection.

- Never use conventional hard contact lens solutions that are not also recommended for use with preservatives.

- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.

- Do not heat the chemical disinfection solution or lenses.

Lens Wearing Precautions
- Never wear lenses beyond the period recommended by the eye care professional.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eyes. If movement of the lens continues, the patient should be instructed to immediately consult his or her eye care professional.

- Avoid, if possible, all hair- or irritating vapors and fumes while wearing lenses.

- If aerosol products are used while wearing lenses, exercise caution and keep eyes open to allow eye liquid to settle.

Lens Care Precautions
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.

- Lens cases should be replaced monthly or as frequently as recommended by the lens care manufacturer or eye care professional.

- When prescribed for a Traditional or Frequent/Planned Replacement lens in the Patient Information Booklet if lens surface does not dry when removed, immediately remove and store the lens container.

- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Always handle lenses carefully and avoid dropping them.

- Do not touch the lenses with fingernails.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb PureVision® for a Traditional or Frequent/Planned Replacement Contact Lens and those prescribed by the eye care professional.

- Never use any other tools or devices to retrieve lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

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

- Eye stinging, burning, itching (irritation), or other eye pain

- Comfort is less than when lens was first placed on eye

- Abnormal feeling of something in the eye (foreign body, scratchy area)

- Excessive watering (tearing) of the eyes

- Redness of the eyes

- Sharpness of vision (poor visual acuity)

- Blurred vision, rainbow, or halos around objects

- Sensitivity to light (photophobia)

- Decreased vision

If 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. If the lens has dirt, an eyelash, or other foreign matter on it, or the patient has any feeling that the lens is damaged, the patient should thoroughly clean, rinse, and disinfect the lenses, then reinsert them. After reinsertion, if the problem persists, the patient should immediately remove the lenses and consult the eye care professional.

- If the above symptoms continue after removal of the lens, or upon insertion of a new lens, the patient should immediately remove the lenses and contact his or her eye care professional or physician, who must determine the need for examination, treatment or referral without delay. (See Lens Care [see Clinical Studies section of the package insert].)
1. Selection of Patients

Persons who require only vision correction and who would not or could not adhere to a recommended care or replacement regimen for Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lenses are unlikely to place and remove the lenses and should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is absolutely necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow professional instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vision, desired lens wearing time (full or part-time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable ocular tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact his or her eye care professional.

2. 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 (consider patient hygiene 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 is compared.

A pre-fitting examination should include spherical refractor and VA, keratometry, biomicroscopic examination.

2. Initial Lens Power & Base Curve Selection

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the 8.7mm base curve lens as the initial lens, (for steeper corneas, start with an 8.8mm base curve lens), and for flatter corneas, start with an 8.9mm base curve) and place the lens on eye.

b. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of flow. Small variations in the tortuosity, corneal and lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

3. Near Add Determination

a. Try on a +1.25 lens on the near eye and observe the reaction.

4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement with an initial lens, and the patient reports lens sensation, or if the lens is moving or decreasing excessively, a steeper base curve should be selected.

Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, or if it becomes uncomfortable, or if the wear schedule is changed, another lens should be selected.

5. Characteristics of a Loose (Flat) Lens

A lens which is too steep may subjectively and objectively cause discomfort which will vary with the blink. However, 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 not tilt to the upper lid, while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If the lens is not relatively stable on post-blink, the lens will remain relatively stable in relationship to the cornea, particularly with the blink.

6. Characteristics of a Loose (Flat) Lens

a. In the initial fitting, check the lens for the following:

• Decenter, especially on post-blink.

• Have a tendency to edge inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.

• Have a tendency to be uncomfortable and irritating with fluctuating vision.

• Have a tendency to drop or lag greater than 2.0mm on upper post blink.

7. Follow-up Care

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From this point on, the following schedule is a suggested guideline for follow up:

- 3 or 4 days post-dispensing
- 10 days
- 1 month
- 3 months
- every six months thereafter

B. Prior to a follow-up examination, the contact lenses should be worn for at least 4 hours continuously and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

C. With lenses in place on the eyes, evaluate fitting performance to assure patient report of the ease of monovision contact lenses, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

D. Papillary conjunctival changes may be indicative of an allergic and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to allow the patient to adjust his or her eye to optimal conditions. If the patient is not able to adjust his or her eye to optimal conditions, the patient should immediately contact the eye care professional.

3. Special Fitting Considerations

a. Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require a distance lens.

Example: A prebyopic myopic patient who requires a +1.75 lens on the near eye and a +1.25 lens on the other eye can experience satisfactory vision.

b. Astigmatic corrections, it is generally best to fit the more myopic (less hyperopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require a distance lens.

Example: A prebyopic myopic patient who requires a +1.75 lens on the near eye and a +1.25 lens on the other eye can experience satisfactory vision.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient’s habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fitting in accordance to the directions in the general fitting procedure.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Most determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct lens power are in place, walk across the room and have the patient look at the patient’s reading distance. Assess the patient’s reaction to distance vision under these circumstances. Once the patient has been observed, remove the patient’s contact lenses at familiar near objects such as a watch face or finger nails. Assess the reaction. As the patient continues to look at familiar near objects, observe the reactions. Only after these vision tasks are completed should be asked to read print. Consider the patient’s reaction to large print (e.g. a newspaper) at first and then gradually to newspaper and finally smaller type sizes.

After the patient’s performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderate illumination should be attempted.

An unfavorable reaction in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.
6. Adaptation
Visually demanding situations should be avoided during the initial wearing period. A patient may at first
experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptive symptoms
to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful
adaptation.
To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.
Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night.
Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile.
During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions.
After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions
The success of the monovision technique may be further improved by having your patient follow the suggestions below:
• Having a third contact lens (distance power) to use when critical distance viewing is needed.
• Having a third contact lens (near power) to use when critical near viewing is needed.
• Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
• Make use of proper illumination when carrying out visual tasks. Success in fitting monovision can be improved by the following suggestions:
  • Reverse the distance and near eyes if a patient is having trouble adapting.
  • Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
  • Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
* The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient’s needs.
* All patients should be supplied with a copy of the SofLens™ 38 (polymacon) Visibility Tinted Contact Lens Disposable Wear Patient Information Booklet or the SofLens™ 38 (polymacon) Visibility Tinted Contact Lens Disposable Wear Patient Instruction Booklet.

HANDLING OF LENSES
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 professional, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear
For complete information concerning the care, cleaning and disinfection of contact lenses refer to the SofLens™ 38 (polymacon) Visibility Tinted Contact Lens Frequent/Planned Replacement Wear Patient Instruction Booklet.

Disposable Wear
For complete information concerning emergency lens care, refer to the SofLens™ 38 (polymacon) Visibility Tinted Contact Lens Disposable Wear Patient Instruction Booklet.

CARE FOR A STICKING (NONMOVING) LENS
If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rehydrating solution in their eyes. 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 professional if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care professional.

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb SofLens™ 38 (polymacon) Visibility Tinted 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
1-800-628-9030
In the Continental U.S., Alaska, Hawaii
1-800-462-9720
In New York State
1-888-459-5000

HOW SUPPLIED
Each sterile lens is supplied in a plastic blister package containing a phosphate buffered saline solution with 0.1% polyvinyl alcohol. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date.