Package Insert / Fitting Guide

BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses

BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Presbyopia

BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Astigmatism

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Name and Address of Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

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

IMPORTANT:
This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses and to illustrate fitting procedures. It is effective as of [date] and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care practitioners, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lens and the recommended wearing schedule.

DESCRIPTION:
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens material, samfilcon A, is a hydrophilic copolymer of a siloxane methacrylate and N-vinyl pyrrolidone, and is 46% water by weight when immersed in a sterile borate buffered saline with poloxamine solution. This lens is tinted blue with up to 200 ppm of Reactive Blue Dye 246. The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses
utilizes MoistureSeal® technology which creates a unique material and a hydrophilic surface.
The physical/optical properties of the lens are:

Specific Gravity: 1.048
Refractive Index: 1.411
Light Transmittance: C.I.E. value – at least 95%
Water Content: 46%
Oxygen Permeability: $114 \times 10^{-11} \text{[cm}^3\text{O}_2\text{STP}/(\text{sec} \times \text{cm}^2 \times \text{mmHg}) \text{]} @ 35^\circ \text{C Polarographic Method (Boundary and Edge Corrected)}$

The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses may be prescribed for Frequent/Planned Replacement or Disposable Wear.

The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Presbyopia features a 3-Zone Progressive™ Design.

The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Astigmatism features an OpticAlign™ Design for stability.

**LENS PARAMETERS AVAILABLE:**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is a hemispherical shell of the following dimensions:

- Diameter: 14.2mm
- Center Thickness: 0.05mm to 0.50mm
- Base Curve: 8.5mm
- Powers (Spherical): +6.00D to –6.00D in 0.25D steps
  -6.00D to -12.00D in 0.50D steps
- Powers (Presbyopia): +6.00D to -10.00D in 0.25D steps
- Add Powers: Low (+0.75D to +1.50D)
  High (+1.75D to +2.50D)

The Bausch + Lomb ULTRA (samfilcon A) Contact Lens for Astigmatism is a hemispherical shell of the following dimensions:

- Diameter: 14.5mm
- Center Thickness: 0.05mm to 0.50mm
- Base Curve: 8.6mm
Sphere Powers: +6.00D to –6.00D in 0.25D steps  
-6.50D to -12.00D in 0.50D steps

Cylinder Powers: -0.75D, -1.25D, -1.75D, -2.25D and -2.75D
Cylinder Axis: 10° to 180° in 10° increments

Additional powers may be introduced over time, check for product availability.

**HOW THE LENS WORKS (ACTIONS):**
In its hydrated state, the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens, when placed on the cornea acts as a refracting medium to focus light rays on the retina.

**INDICATIONS:**

**Single Vision Spherical (SVS) Vision Correction**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

**Presbyopia Vision Correction**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Presbyopia is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D.
Astigmatism Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Astigmatism is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient’s eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is to be discarded after each removal.
CONTRAINDICATIONS (REASONS NOT TO USE):  
Do not use these 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 eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) 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 which is to be used to care for the BAUSCH + LOMB ULTRA (samfilcon A) 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 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 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 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.
- 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 lenses are worn overnight.
- When prescribed for 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 should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

Extended Wear
- The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea’s resistance 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; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens
deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants.

• While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and endothelial 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, practitioners’ views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods up to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

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

PRECAUTIONS:
Special Precautions for Eye Care Practitioners:

• Due to a 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 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 prescribing eye care practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.

• Eye care practitioners should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.

• 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 sterile saline solution that is recommended for in-eye use.
• The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the wearing schedule recommended by the eye care practitioner.

• 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.

• Aphakic patients should not be fitted with BAUSCH + LOMB ULTRA (samfilcon A) contact lens until the determination is made that the eye has healed completely.

• Patients who wear these lenses 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.

Eye care practitioners 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 Bausch + Lomb ULTRA (samfilcon A) Contact Lens Patient Information Booklet available from Bausch + Lomb and understand its contents prior to dispensing the lenses.

**Handling Precautions:**

• 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 products.

• Be sure that before leaving the eye care practitioner’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 injury to the eye.

• Always handle lenses carefully and avoid dropping them.

• Do not touch the lens with fingernails.

• Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens and those prescribed by the eye care practitioner.

• 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.
Lens Wearing Precautions:
• Never wear lenses beyond the period recommended by the eye care practitioner.
• 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 eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
• Avoid 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:
• 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 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.
• You should fill your lens case with fresh solution every time you store your lenses, and never “top-off” or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case.
• Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). 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 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 prescribed lenses.
• 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 Case 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 at regular intervals as recommended by the lens case manufacturer or eye care practitioner.
Topics to Discuss with the Patient:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform all your doctors (Health Care Professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

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
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- 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 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 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.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care practitioner** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications

**Important Treatment Information for Adverse Reactions**

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. 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, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

**SELECTION OF PATIENTS:**

The eye care practitioner should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses 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 also 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 ULTRA (samfilcon A) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.
A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, 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 vision, occasional 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 practitioner.

PRACTITIONER FITTING SETS:
Lenses must be discarded after a single use and must not be used from patient to patient.

GENERAL 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 results can be compared.

A prefitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection
• A spectacle refraction should be performed to establish the patient’s baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than 4.00D.

3. Initial Lens Evaluation
   a. To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
      Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics. The time required will vary with the individual.
• Movement: The lens should provide discernible movement with:
  - Primary gaze blink
  - Upgaze blink
  - Upgaze lag
• Centration. The lens should provide full corneal coverage.

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 after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

4. **Criteria of a Well-Fitted Lens**

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

5. **Characteristics of a Tight (Steep) Lens**

A lens which is much too steep may subjectively and objectively cause distortion which 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 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

Toric lens: With your finger, gently rotate the lens approximately 45° to the temporal side. It should reorient with 5 to 10 blinks back to the same stabilized position.

6. **Characteristics of a Loose (Flat) Lens**

A lens that is too flat will decenter, especially on post-blink, have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva. A flat fitted lens will have a tendency to be uncomfortable and irritating with fluctuating vision. A flat fitted lens has a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. **Follow-up Care**

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow up.
  - 24 hours
  - 1 to 2 weeks
• Every 12 months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. Depending on the patient’s prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
   1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
   2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
   3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

   If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

TORIC FITTING GUIDELINES:

a. Determine contact lens power. The toric trial lens is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction. It is preferable to use the spectacle R$_s$ as the basis for the contact lens power. The sphere and cylinder power of the spectacle R$_s$ becomes the closest sphere and cylinder power of the contact lens.

   There are two exceptions:
   1. If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient's subjective responses.
Example: Spectacle Rx: -2.00-1.00 X 180
Contact Lens Power Ordered: -2.25-0.75 X 180

2. When the spectacle lens power in any principle meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.
   Example: Spectacle Rx: -5.00-2.75 X 180
            Contact Lens Power Ordered: -4.75-2.25 X 180
   b. Determine contact lens axis, the center guide mark should locate at the Inferior limbus. Once oriented, rotational rocking should be limited to less than 5°.
   c. Allow the lens to settle for at least 3 minutes to achieve a state of equilibrium. Note the orientation of the guide mark relative to the vertical meridian. Regardless of which eye the lens is on, if the rotation is clockwise but stable, note the amount of rotation, add it to the refractive cylinder axis and order the resulting axis. If the rotation has stabilized counterclockwise, again note the rotation, subtract it from the refractive axis and order the resulting axis. The guide mark can be used to help you calculate the axis of the desired Rx lens.
      Example: Spectacle Rx: -2.50-1.25 X 80
                Rotation: 20° clockwise
                Final Lens Prescription: -2.50-1.25 X 100
   d. Select patient's lenses.
   e. Evaluate orientation of final Rx lenses. The orientation of the prescription should be the same as that observed for the Fitting Set Lenses. For example, if the lens rotated clockwise 15° then the final prescription lens should also rotate clockwise 15°.

MULTIFOCAL FITTING GUIDELINES:
1. Lens Selection
   a. Update spectacle refraction and Add power.
   b. Determine ocular dominance for distance vision.
   c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.
   d. Choose trial lenses based upon the above calculation and select Add power.
      • Bausch + Lomb ULTRA for Presbyopia Low Add: +0.75D to +1.50D
      • Bausch + Lomb ULTRA for Presbyopia High Add: +1.75D to +2.50D

2. Lens Fitting
   a. Allow lenses to equilibrate for at least 10 minutes before assessing fit and vision.
   b. Evaluate distance and near vision binocularly in normal room illumination.
   c. If vision at distance and near are satisfactory, dispense lenses and schedule follow-up exam within 1-2 weeks.
3. To refine Near Vision
If patient is wearing two Low Add lenses:
   • Refinement 1:
     Place Bausch + Lomb ULTRA for Presbyopia High Add in non-dominant eye while keeping Bausch + Lomb ULTRA for Presbyopia Low Add in dominant-eye.
   • Refinement 2:
     If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.
If patient is wearing two High Add lenses:
   • Refinement 1:
     Add +0.25D to the non-dominant eye.
   • Refinement 2:
     If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

4. To refine Distance Vision:
If patient is wearing two Low Add lenses:
   • Refinement 1:
     Fit Bausch + Lomb ULTRA SVS in dominant eye while keeping Bausch + Lomb ULTRA for Presbyopia Low Add in non-dominant eye.
   • Refinement 2:
     If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in satisfactory.
If patient is wearing two High Add lenses:
   • Refinement 1:
     Fit with Bausch + Lomb ULTRA for Presbyopia Low Add in dominant eye while keeping Bausch + Lomb ULTRA for Presbyopia High Add in non-dominant eye.
   • Refinement 2:
     If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision in satisfactory.

5. Patient Education
All patients do not function equally well with multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that multifocal contact lenses provide.
MONOVISION FITTING GUIDELINES:

1. **Patient Selection**
   a. **Monovision Needs Assessment**
   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens.

   Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

   1. Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
   2. Driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

   b. **Patient Education**
   All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. **Eye Selection**
   Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used:
   A. **Ocular Preference Determination Methods**
   Method 1 – Determine which eye is the “sighting dominant eye.” Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
   Method 2 – Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.
B. Refractive Error Method
For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method
Consider the patient’s occupation during the eye selection process to determine the critical vision requirements. If a patient’s gaze for near tasks is usually in one direction correct the eye on that side for near.
Example:
A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

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 only a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.
A presbyopic patient requiring a +1.50 diopter add who is −2.50 diopters myopic in the right eye and −1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

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 fit according to the directions in the general fitting guidelines.

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. Next 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 power lenses are in place, walk across the room and have the patient look at you. Assess the patient’s reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distant objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient’s reaction to large print (e.g. typewritten copy) at first and then graduate to newsprint 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 moderately dim illumination should be attempted.

An initial unfavorable response 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 adaptational 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 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 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 is 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 practitioner in conjunction with the patient after carefully considering the patient’s needs.
All patients should be supplied with a copy of the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens Patient Information Booklet.

WEARING SCHEDULE:
The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups as determined by the eye care practitioner are extremely important.

Daily Wear:
There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily 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.

Continuous Wear (greater than 24 hours or while asleep):
Bausch + Lomb recommends the contact lens wearer first be evaluated on a daily wear schedule. If successful, then gradual introduction of extended wear can be followed as determined by the prescribing eye care practitioner.

These lenses have been approved for extended wear for up to 7 days. 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 warnings section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the eye care practitioner.

Disposable Lens Wear:
No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Frequent/Planned Replacement:
When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

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 practitioner 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 BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens Patient Information Booklet.
a. Soaking and Storing Lenses
Instructions for Use:
Use only fresh contact lens disinfecting solution each time you soak (store) your 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.

b. Rub and Rinse Time
Instructions for Use:
- Follow 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 serious infection, vision loss or blindness.

c. Lens Case Care
Instructions for Use:
- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solution/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 lens case according to the directions given by your eye care practitioner 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.

d. Water Activity
Instructions 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 for recommendations about wearing lenses during any activity involving water.

e. Discard Date on Solution Bottle
Instructions for Use:
Discard any remaining solution after the recommended time period indicated on the bottle of the 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.

Disposable Wear: For complete information concerning emergency lens care, refer to the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens Patient Information Booklet.

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, and to not attempt to remove the lens except on the advice of the eye care practitioner.

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses or experienced with the lenses should be reported to:

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

**Toll Free Telephone Number**
In the Continental U.S., Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 – English, Option 2 – French)

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

**SYMBOL REFERENCE GUIDE FOR LABEL AND CARTONS:**
Quality System Certification Symbol

Fee Paid for Waste Management

Sterile Using Steam or Dry Heat

See Instruction Leaflet

Storage Temperature

Diameter

Use by Date (expiration date)

Batch Code

Diopter (lens power)

Authorized representative in European Community

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

Base Curve

Single Vision Spherical

Low or High Add Power

Cylinder Axis (Degrees)

Cylinder Power (Diopters)

Sphere Power (Diopters)

Effective Date

Patient Information Booklet

BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses
BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Presbyopia

BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses For Astigmatism

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**CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.

**Introduction**

The instructions in this booklet apply to the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses. If you have received or are considering another brand of contact lenses, do not use this
booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear, you should discuss with your eye care practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses, which are greater with continuous wear contact lens use. You also should read the sections of this booklet entitled “Warnings”, “Adverse Reactions”, “Precautions”, and “Wearing Restrictions and Indications”. Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care practitioner.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in the sections of this booklet entitled “Personal Cleanliness and Lens Handling”, as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a buildup of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing and replacement schedule, and regular check-up visits to your eye care practitioner are also necessary for the proper and safe use of contact lenses.

**It is important to not wear your lenses longer than recommended by your eye care practitioner since doing so increases the risk of adverse effects.**

Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not wear your lenses for longer periods than your prescribed wearing schedule simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.
If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the sections of this booklet entitled “Warnings” and “Adverse Reactions”. (Refer to “Glossary of Medical Terms” for descriptions of medical terms used in this booklet). Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

**Wearing Restrictions and Indications**

**SVS Vision Correction**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

**Presbyopia Vision Correction**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Presbyopia is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D.

**Astigmatism Vision Correction**
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens For Astigmatism is indicated for daily wear or extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

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**FREQUENT/PLANNED REPLACEMENT WEAR**
When prescribed for Frequent/Planned Replacement Wear, the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient’s eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.
WEARING RESTRICTIONS
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses technology described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner. For extended wear, once the lenses are removed, your eyes should have a rest without lens wear for at least one overnight, as recommended by your eye care practitioner. Your eye care practitioner will tell you how long to rest your eyes in between wearing periods and will also recommend a replacement period and appropriate lens care products.

Contraindications
(Reasons Not To Use)
DO NOT USE these 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 eyes)
• Corneal hypoesthesia (reduced corneal sensitivity)
• Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
• Allergic reactions of ocular surfaces or adnexa (surrounding tissue) 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 which is to be used to care for BAUSCH + LOMB Ultra® (samfilcon A) Contact Lenses
• Any active corneal infection (bacterial, fungal, or viral)
• If eyes become red or irritated

Warnings
You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:
• Problems with contact lenses and lens care products could result in serious injury to your eye. It is essential that you follow your 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.
• Strict compliance with your lens care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.
• Daily wear lenses are not indicated for overnight wear, and you should not wear 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.
Extended Wear

- The risk of microbial keratitis has been shown to be greater among users of continuous wear contact lenses than among users of daily wear contact lenses.

Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea’s resistance 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; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants.

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

- The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners’ views of continuous wearing times vary from not prescribing continuous wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing continuous wearing periods from up to 7 days with specified
intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove lenses and promptly contact your eye care practitioner.

**Precautions**

You should be aware of and fully discuss with your eye care practitioner the following lens care regimen and safety precautions:

**Specific Precautions:**
- Always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.

**Handling Precautions:**
- 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 products.
- Before leaving your eye care practitioner’s office be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle your lenses carefully and avoid dropping them.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eye care practitioner.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

**Lens Wearing Precautions:**
- Never wear your lenses beyond the period recommended by your eye care practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Avoid all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

**Lens Care Precautions:**

NOTE: 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, 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.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens 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 prescribed lenses.
- 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 Case 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 at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

**Topics to Discuss with the Eye Care Practitioner:**

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. You should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Always contact your eye care practitioner before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
**Who Should Know That the Patient is Wearing Contact Lenses:**

- Inform all your doctors (Health Care Professional) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear lenses.

Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________
Adverse Reactions
(Problems And What To Do)
You should be aware 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
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above:
- **Immediately remove your 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 your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should **immediately remove the lenses and consult your eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off your eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.**

Personal Cleanliness and Lens Handling

1. **Preparing the Lens for Wearing:**
   It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. **Cleanliness is the first and most important aspect of proper contact lens care.** In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:
   - Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
   - Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with
successful wearing.

• Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

• Develop the habit of always working with the same lens first to avoid mixups.
• Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
• Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.
  a. Less than usual comfort
  b. The lens may fold on the eye
  c. Excessive lens movement on blink
  d. Blurred vision
• If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from Bausch & Lomb.) Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.
• If this gentle rubbing does not work, soak the lens in the recommended solution in your lens case until the lens has resumed its normal shape. If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.
• Keep the lens wet in the solution recommended by your eye care practitioner.
• Never place a lens on the eye unless it has been fully hydrated (wet) with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from Bausch + Lomb.)

3. Placing the Lens on the Eye:

There are other methods of lens placement. If the following methods are difficult for you, your eye care practitioner will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:
• The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
• If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
  a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
  b. The lens is on the wrong eye.
  c. The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both
lenses and consult your eye care practitioner.

**The One Hand Placement Technique**
Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment; the will center itself on your eye.

![Image of one hand placement technique]

**The Two hand Placement Technique**
With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

![Image of two hand placement technique]

If the lens feels uncomfortable, then:
Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled “Adverse Reactions.”

4. Centering the Lens:
Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

Or

- Hold the upper and lower eyelids open with your fingers. Then while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

5. Removing the Lens:
Always remove the same lens first.

a. Wash, rinse, and dry your hands thoroughly.
b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.
c. Remove the other lens by following the same procedure.
d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

LENS WEARING SCHEDULES:
Your eye care practitioner may either recommend using the BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses as a disposable lens or a frequent/planned replacement lens.

Regardless of the schedule prescribed for you, once a lens is removed at the end of the prescribed wearing period, your eye should have a rest period with no lens wear of overnight or longer, as recommended by your eye care practitioner.

Daily Wear:
There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily 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.

**Continuous Wear (greater than 24 hours or while asleep):**
Bausch + Lomb recommends the contact lens wearer first be evaluated on a daily wear schedule. If successful, then gradual introduction of extended wear can be followed as determined by the prescribing eye care practitioner.

These lenses have been approved for extended wear for up to 7 days. 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 warnings section.) **Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the eye care practitioner.**

**Disposable Lens Wear:**
No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

**Frequent/Planned Replacement:**
When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion or be discarded and replaced with a new lens.
Caring for Your Lenses
(Cleaning, Rinsing, Disinfecting, Enzyming, Storage and Rewetting/Lubricating)

For continued safe and comfortable wearing of your lenses, it is important that you follow the lens care regimen recommended by your eye care practitioner. Failure to follow the lens care regimen may result in development of serious ocular complications as discussed in the WARNINGS section above. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

If you require only vision correction, but will not or cannot adhere to a recommended lens care regimen, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

You should adhere to the lens care regimen recommended by you eye care practitioner. Failure to follow the lens care regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

When you first get your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of these Patient Instructions for BAUSCH + LOMB ULTRA (samfilcon A) Soft (hydrophilic) Contact Lens.

1. Soaking and Storing Lenses
   Instructions for Use:
   Use only fresh contact lens disinfecting solution each time you soak (store) your 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 sever infection, vision loss or blindness. “Topping-off” is the addition of fresh solution to solution that has been sitting in the case.

2. Rub and Rinse Time
   Instructions for Use:
Follow 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 serious infection, vision loss or blindness.

3. **Lens Case Care**
   **Instructions for Use:**
   - Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solution/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 lens case according to the directions given by your eye care practitioner 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 sever infection, vision loss or blindness.

4. **Water Activity**
   **Instruction for Use:**
   Do not expose contact lenses to water while wearing them.

**WARNING:**
Water can harbor microorganisms that can lead to sever 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 for recommendations about wearing lenses during any activity involving water.

5. **Discard Date on Solution Bottle**
   **Instructions for Use:**
   Discard any remaining solution after the recommended time period indicated on the bottle of the 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.

5. Basic Instructions
For safe contact lens wear, you should know and always practice your lens care routine:
• Always wash, rinse, and dry hands before handling contact lenses.
• Always use fresh, unexpired lens care solutions.
• Use the recommended chemical (not heat) lens care system 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.
• Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
• Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
• Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period prescribed by your eye care practitioner.
• Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b. You might lose the lens down the drain.
• 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. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
• After cleaning, and rinsing, disinfect lenses using the system recommended by your eye care practitioner. Follow the instructions provided in the disinfection solution labeling.
• To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
• Your eye care practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

6. Chemical (Not Heat) Disinfection:
• Clean the contact lenses with the cleaning solution recommended by your eye care practitioner and thoroughly rinse them with the recommended rinsing solution.
• **After cleaning**, and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by your eye care practitioner.

• When using hydrogen peroxide lens care systems, lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.

• Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.

• **Do not heat the disinfection solution and lenses.**

• Leave the lenses in the closed storage case until ready to put on your eyes.

• **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to your eyes. A thorough rinse in fresh sterile saline solution prior to placement on your eye should reduce the potential for irritation.

7. **Lens Deposits and Use of Enzymatic Cleaning Procedure:**
   Enzyme cleaning may be recommended by your eye care 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 your 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, you should carefully follow the instructions in the enzymatic cleaning labeling.

8. **Care for a Sticking (Nonmoving) Lens:**
   It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner into your eye. Do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately. Do not attempt to remove the lens except on the advice of your eye care practitioner.

9. **Care for a Dried Out (Dehydrated) 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, apply the recommended rinsing solution before handling.

**To rehydrate the lens:**

• Handle the lens carefully.

• Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.

• Clean lens first, then disinfect the rehydrated lens using a recommended lens care system.
• If after soaking, the lens does not become soft or if the surface remains dry, DO NOT USE THE LENS UNTIL IT HAS BEEN EXAMINED BY YOUR EYE CARE PRACTITIONER.

Emergencies
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

Lens Care Products Chart
The following solutions are available from Bausch + Lomb for use with all Bausch + Lomb Contact Lenses; however, eye care practitioners may recommend alternative products and procedures which should be followed by the patient. Bausch + Lomb Care Kits are available for lens disinfection, cleaning, and storage.
Chemical Lens Care System

<table>
<thead>
<tr>
<th>ACTION</th>
<th>CARE PRODUCT</th>
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<tbody>
<tr>
<td>Cleaning</td>
<td>Bausch + Lomb renu® fresh multi-purpose solution</td>
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<tr>
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<td>Bausch + Lomb renu® sensitive multi-purpose solution</td>
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<td>Bausch + Lomb Sensitive Eyes® Daily Cleaner</td>
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<td>Bausch + Lomb Biotrue® multi-purpose solution</td>
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<td>Bausch + Lomb renu® Advanced Formula multi-purpose solution</td>
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<tr>
<td>Disinfecting &amp; Storing</td>
<td>Bausch + Lomb renu® fresh multi-purpose solution</td>
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<td>Bausch + Lomb renu® sensitive multi-purpose solution</td>
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<td>Bausch + Lomb renu® Advanced Formula multi-purpose solution</td>
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<tr>
<td>Rinsing</td>
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<td>Bausch + Lomb renu® sensitive multi-purpose solution</td>
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<td></td>
<td>Bausch + Lomb Sensitive Eyes® Plus Saline Solution</td>
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<tr>
<td></td>
<td>Bausch + Lomb Biotrue® multi-purpose solution</td>
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<td></td>
<td>Bausch + Lomb renu® Advanced Formula multi-purpose solution</td>
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<tr>
<td>Rewetting</td>
<td>Bausch + Lomb renu® MultiPlus lubricating &amp; rewetting drops</td>
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<tr>
<td></td>
<td>Bausch + Lomb renu® rewetting drops</td>
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<td></td>
<td>Bausch + Lomb Sensitive Eyes® Drops</td>
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Note: Some solutions may have more than one function in the care regimen, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Instructions for the Monovision Wearer

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.
- Some patients have experienced difficulty adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.
- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
• Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
• If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
• Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this option with your eye care practitioner.
• It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
• The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.

**Personal Wearing Schedule Record**
Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record.

<table>
<thead>
<tr>
<th>DAY</th>
<th>DATE</th>
<th>HOURS TO BE WORN</th>
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Check-Up Visits
Regular check-up examinations by your eye care practitioner are an important part of wearing contact lenses. It is recommended that you follow your eye care practitioner’s directions for follow up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location. Use the space below to record your appointments.

Visit Schedule

1. ___________________________________________  ______________________
   Date                                       Time

2. ___________________________________________  ______________________
   Date                                       Time

3. ___________________________________________  ______________________
   Date                                       Time

4. ___________________________________________  ______________________
   Date                                       Time

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   Date                                       Time

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   Date                                       Time

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   Date                                       Time

8. ___________________________________________  ______________________
   Date                                       Time

9. ___________________________________________  ______________________
   Date                                       Time

10. ____________________________________________  ______________________
    Date                                       Time
Eye Care Practitioner Information
(Please fill out for ready use)

Name: ____________________________________________
Address: _______________________________________
Phone: _________________________________________
Other Information: _______________________________________

Important: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY.
Glossary of Medical Terms

Ametropia - Abnormal vision requiring correction for proper focus
Myopia - Nearsighted
Hyperopia - Farsighted
Aphakic - Lacking a crystalline lens (focusing lens inside the eye)
Non-aphakic - Not lacking a crystalline lens
Acute inflammation - Sudden swelling, redness and pain
Subacute inflammation - Gradual swelling, redness and pain
Anterior chamber - Internal portion of the eye, between the cornea and iris
Cornea - Clear, front covering of the eye
Conjunctiva - Membrane that lines the eyelids and the white part of the eye
Corneal ulcer - A sore or lesion on the cornea, which left untreated could lead to permanent loss of vision
Microbial keratitis - An infected corneal ulcer
Hypoxia - Lack of oxygen
Epithelial - Layer of cells on the surface of the cornea
Epithelial microcysts - A small abnormal structure (cyst) in the front surface of the eye
Endothelial polymegathism - Irregular cell size and shape
Neovascularization - Small blood vessels growing into the cornea
Iritis - Internal inflammation of the colored part of the eye (iris)

Name and Address of Manufacturer:
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609
Symbol Reference Guide

For labels and cartons:

- **Quality System Certification Symbol**
- **Fee Paid for Waste Management**
- **Sterile Using Steam or Dry Heat**
- **See Instruction Leaflet**
- **Storage Temperature**
- **Diameter**
- **Use By Date (expiration date)**
- **Batch Code**
- **Authorized representative in European Community**
- **Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.**
- **Dioptr (lens power)**
- **Base Curve**
- **Low or High Add Power**
- **Cylinder Axis (Degrees)**
- **Cylinder Power (Diopters)**
- **Sphere Power (Diopters)**
- **Effective Date**

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