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 concerning characteristics of the Bausch + Lomb ULTRA (samfilcon A) Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and superseded all prior fitting guides for the product described.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 practitioner, 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.

CONTRAINDICATIONS (REASONS NOT TO USE)

DONOT USE the Bausch + Lomb ULTRA (samfilcon A) Contact Lens, Bausch + Lomb ULTRA (samfilcon A) Contact Lens For Presbyopia, and Bausch + Lomb ULTRA (samfilcon A) Contact Lens For Astigmatism when any of the following conditions exist:

• Acute and subacute infection or inflammation of the anterior chamber of the eye
• Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or episclera
• Severe deficiency of lacrimal secretion (dry eyes)
• Corneal hypotony (reduced corneal sensitivity)
• Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses
• Allergic reactions of ocular surfaces or adhesions (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)
• Eyes become red or irritated.

HOW THE LENSES 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.
The technology which creates a unique material and a hydrophilic surface.

The Bausch + Lomb UL TRA (samfilcon A) Contact Lens For Presbyopia features Frequent/Planned Replacement or Disposable Wear.

degree of epithelial microcysts and infiltrates, and endothelial polymegathism, wear of lenses also is reported to be associated with a higher incidence and the risk of microbial keratitis has been shown to be greater among users of

• If a patient experiences eye discomfort, excessive tearing, vision changes, or any of the following problems may occur:

ADVERSE REACTIONS

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

• Always use fresh, unpreserved lens solutions.

• Always follow directions in the package insert for the use of contact lens solutions.

• Store 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. As a result, all lens solutions completely in the recommended storage solution when lenses are not being worn (closed). Storlapsed periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet (items surface does become dried out).

• Do not dilute or add anything other than the recommended solution for lubricating or wetting agents.

• Tap, droplet 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 Ascanthamoeba keratitis.

• 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 or microwave disinfection solution or lens case.

Lenses Card Care

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

• Lenses should be replaced at regular intervals as recommended by the lens care manufacturer or eye care practitioner.

SELECTION OF PATIENTS

This care practitioner should not fit patients who cannot or will not adhere to a recommended contact lens regimen or care. In order to avoid the use of lenses that are not properly stored, the lens case should be exchanged every three months. Patients should be educated about the importance of exchanging their lens case regularly and maintaining good lens care habits.

• Patients should be counseled that failure to adhere to the lens care instructions may result in serious or permanent eye injury. Contact lens wearers who wish to quit should be advised to gradually discontinue wearing their lenses and return for follow-up care and counseling.

• Patients should be advised that if their vision does not improve, the lens care practitioner should be consulted.

• Patients should be advised to wear their lenses and contact their eye care practitioner immediately if:

• If a patient experiences eye discomfort, excessive tearing, vision changes, or any of the following problems may occur:

• Patients who wear aphakic contact lenses, such as the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses for presbyopia, 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 lenses 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 Lenses Patient Information Booklet available from Bausch + Lomb and understands 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 spray on the eyes or on the lens. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products of them. Be sure that before leaving the eye care practitioner’s office, the patient is able to remove lenses remotely 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 lens may cause distorted vision and/or injury to the eye. Always handle lenses carefully and avoid dropping them.

• Be careful handling the lens, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses 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. For the lens into the hand.

• Lenses 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 (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If movement of the lens continues, the patient should contact his or her eye care practitioner.

• Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.

• If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

• Be sure that before leaving the eye care practitioner’s office, the patient is able to remove lenses remotely 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 lens may cause distorted vision and/or injury to the eye. Always handle lenses carefully and avoid dropping them.

• Be careful handling the lens, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb ULTRA (samfilcon A) Contact Lenses 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. For the lens into the hand.

• Lenses 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 (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If movement of the lens continues, the patient should contact his or her eye care practitioner.

• Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.

• If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

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### 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’s hygiene and mental and physical status).
  - 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.

#### 2. Initial Lens Power Selection
- A spectacle refraction should be performed to establish the patient’s baseline refractive status and to guide 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. Determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
- b. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variations in the tonicity 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 be capable of discomposing with:
    - Primary gaze blink
    - Upgaze blink
    - Upgaze lag
  - Centration: The lens should provide full corneal coverage
- c. 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. 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 visual, or if the lens shows insufficient movement, the lens should not be dispensed.

### 4. Criteria of a Well-Fitted Lens
If the lens fully covers the cornea, provides discernible movement after a blink, is comfortable to the patient, and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

### 5. Characteristics of a Tight (Sleep) Lens
A lens which is much too tight may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally tight, the initial subjective and objective vision and comfort findings may be quite good. Marginally loose lenses may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.32mm while a sleep lens will remain relatively stable in relationship to the cornea, particularly with the blink. Toric Lenses: With your finger, gently rotate the lens approximately 45° to the temporal side. It should slide between 0.1 to 0.3mm back to the same stabilized position.

### WEARING SCHEDULE

#### Unilateral Lens Correction

- **To Refine Near Vision**
  - a. Soaking and Storing Lenses
    - Insufficient movement, the lens should not be dispensed.
    - 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 Lenses are not satisfied during any follow-up examination, the patient should be referred to a more appropriate lens.
  - b. Determine contact lens power
    - The toric trial lens is utilized to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction. It is preferable to use the spectacle Rx as the basis for the contact lens powers. The sphere and cylindrical power of the spectacle Rx becomes the closest lens of contact.
    - **There are two exceptions:**
      1. If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lower contact lens cylinder power. The sphere power can then be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient’s subjective responses.
      2. When the spectacle lens power in any principle meridian is greater than 4.00D, the spectacle refraction should be verified to the corneal plane. This can affect both in the sphere and cylinder powers.

#### 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 six months thereafter**
- b. At the initial follow-up examination 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 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.
- c. Prior to a follow-up appointment, the following examination should be conducted as early as possible the morning after overnight wear.

### TOTC FITTING GUIDELINES

#### 1. Patient Selection
- a. Monovision Needs Assessment
  - A patient should have adequately corrected distance and near vision by the use of glasses. An amblyopic patient or the patient with significant astigmatism (greater than 4.00D in one eye) is not a good candidate for monovision with the Bausch + Lomb ULTRA lens. Contact Lenses.
  - *C* uational and environmental visual demands should be considered. If the patient requires or local visual (visual acuity and stereoacuity) it should be determined by trial whether this patient can function adequately with monovision.
  - *C* onnected contact lens wear may not be optimal for such activities as:
    - *V* isually demanding situations such as operating potentially dangerous machines, or performing other potentially hazardous activities.
    - *D* riving automobiles (e.g., driving at night). Patients who cannot pass their driver’s test a driver’s license requirements may experience monovision should be advised not to drive with this monovision correction. OR may require that additional over-correction be prescribed.
- b. **Patient Education**
  - All patients do not function equally well with multi-focal correction. Patients may perform as well for certain tasks with the correction as they have with multi-focal reading glasses. Each patient should understand that multi-focal 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 multi-focal 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 vision in each eye.
  - The amblyopic patient or the patient with significant astigmatism (greater than 4.00D in one eye) is not a good candidate for monovision with the Bausch + Lomb ULTRA lens. Contact Lenses.
  - The patient requires or local visual (visual acuity and stereoacuity) it should be determined by trial whether this patient can function adequately with monovision.

#### 2. Eye Selection
- Generally, the non-dominant eye is corrected for near vision. The following text for eye dominance can be used.
  - *O* ular Preference Determination Methods:
    - **Method 1—Determine which eye is the “slightly 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 (lighting) eye.
    - **Method 2—Determine which eye will accept the added power with the near add lens over the right or left eye.** Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.
  - **Subtractive Error Method** for astigmatic corrections. It is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.
  - **Visual Demand Method**
    - Consider the patient’s occupation during the eye selection process to determine the visual requirement. If the patient’s near task 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 better with the near lens on the left eye.

### HANDLING OF LENS

- **A** daptation prior to beginning continuous wear.
- **B** efore the patient’s performance under the above conditions is completed, tests of
- **C** omfort, vision, and can lead to severe infection, vision loss or blindness.
- **D** o not store lenses or rinse lens case with water or any non-sterile solution. Only
- **E** xamine the lenses closely
- **F** or surface deposition and/ or damage.
- **G** rade of an unclean and/ or damaged lens.
- **H** ighly contagious can be indicative of an unclean lens, a reaction to solution preservatives, excessive wear lenses, and/or a poorly fitting lens.
- **I** nitially differentiate from a properly fitted lens by having the patient gaze upward and irritating with fluctuating light. A flat fittleness has a tendency to drop or be greater than 2.0mm on upgaze post blink.
- **J** ustification can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient’s subjective responses.
- **K** ickly discriminating can lead to severe infection, vision loss or blindness.
- **L** evel of satisfaction in straight ahead and upward gaze that multi-focal contact lenses provide.
- **M** any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions.
- **N** atural eye infections.
- **O** bserve the reaction to this mode of correction.
- **P** reference Determination Methods:
  - **Method 1—Determine which eye is the “slightly 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 (lighting) eye.
  - **Method 2—Determine which eye will accept the added power with the near add lens over the right or left eye.** Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.
  - **Subtractive Error Method** for astigmatic corrections. It is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.
  - **Visual Demand Method**
    - Consider the patient’s occupation during the eye selection process to determine the visual requirement. If the patient’s near task 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 better with the near lens on the left eye.
  - **Method 2—Determine which eye will accept the added power with the near add lens over the right or left eye.** Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.
  - **Subtractive Error Method** for astigmatic corrections. It is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.
  - **Visual Demand Method**
    - Consider the patient’s occupation during the eye selection process to determine the visual requirement. If the patient’s near task 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 better with the near lens on the left eye.
  - **Method 2—Determine which eye will accept the added power with the near add lens over the right or left eye.** Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.
  - **Subtractive Error Method** for astigmatic corrections. It is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.
  - **Visual Demand Method**
    - Consider the patient’s occupation during the eye selection process to determine the visual requirement. If the patient’s near task 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 better 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 enophtalmic patient would only require one near lens while a bilateral myopic may require only a distance lens.

Example:

A pseudophakic patient requiring a +1.75 sph contact lens would require a +1.75 sph lens on the near eye and the other eye (left without a lens).

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.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 24 hours.

c. Allow the lens to settle for at least 3 minutes to achieve a state of equilibrium.

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the inferior limbus. Once oriented, rotational rocking should be limited to less than 2.0mm on upgaze post-blink.

4. Criteria of a Well-Fitted Lens

The success of the monovision technique may be further improved by having your contact lens care practitioner.

a. Fit Bausch + Lomb ULTRA SVS in dominant eye while keeping the recommended lens axis rotated clockwise 15° then the final prescription lens should also be the same as that observed for the trial lenses.

b. Determine contact lens axis, the center guide mark should locate at the pupil midline of the patient’s dominant eye.

c. Visual Demands Method

For anisometropic corrections, it is generally best to fit the more hyperopic eye for distance and the more myopic eye for near.

- Method 1—Determine which eye will accept the added power with the contact lens on the eye.

- Method 2—Determine which eye will accept the added power with the contact lens on the opposite eye.

1. Pre-Fitting Examination

PRACTITIONER FITTING SETS

2. When the spectacle lens power in any principle meridian is greater than 2.0D, it is best to fit the more hyperopic or myopic eye for distance and the less hyperopic or myopic eye for near.

3. Papillary conjunctival changes may be indicative of an unclean and/or insufficient movement, the lens should not be dispensed.

CASE HISTORY AND STANDARD CLINICAL EVALUATION PROCEDURE

The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lenses’ characteristics and system selected by the professional. The specific instructions for such products and the particular characteristics of the patient should be included in the Practice Considerations section of the directions given by your eye care practitioner or the labeling that came with the case.

Contact lens care practitioners should be the first to evaluate the patient after carefully considering the patient’s needs.

- Do not store contact lenses or rinse case with or any non-stereile 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.

- Replace lens case according to the directions given by your eye care practitioner or the labeling that came with the case.

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; verify that the patient looks at familiar near objects such as a watch face or fingerprints. 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., typed or cursive) 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

Visual demand 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 adaptation 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 in a car 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 an alert contact lens (distance power) to use when critical distance viewing is needed.

- A trial contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

- Success in fitting monovision can be improved by the following suggestions:

  - Reverse the distance and near eyes if a patient is having trouble adapting.
  
  - Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for pseudophakic patients.
  
  - Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

- The decision to fit a patient with a monovision correction is most appropriately left to the eye care 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.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (steps 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 up on 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
1640 North Goodman Street
Rochester, New York 14607 USA
Tel: Free Telephone Number
In the Continental U.S., Alaska, Hawaii 1-800-353-5340
In Canada 1-800-459-5000 (Option 1 - English, Option 2 - French)

HOW SUPPLIED

Each sterile lens is supplied in a plastic blister pack containing sterile 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.

HANDLING OF LENS

Patient Lens Care Directions

- Clean contact lenses 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 contact lens cases 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 the case.

- Contact lens cases can be a source of bacterial growth.

- WARNING:
  - Do not store contact lenses or rinse case with 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.
  - Water Activity
  - Instructions for Use:
  - Do not expose contact lenses to water while wearing them.

- 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

- Instruct the patient to discard any remaining solution after the recommended time period indicated on the bottle of the solution used for disinfecting and cleaning 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.

- WARNING:
  - Do not exceed contact lenses (distance power) to use when critical distance viewing is needed.

- Having a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

- Success in fitting monovision can be improved by the following suggestions:

  - Reverse the distance and near eyes if a patient is having trouble adapting.
  
  - Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for pseudophakic patients.
  
  - Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

- The decision to fit a patient with a monovision correction is most appropriately left to the eye care 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 schedule 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 rust 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 Wear

When removed between replacement periods, lenses must be cleaned and disinfected before reininsertion, or be discarded and replaced with a new lens.