Acute and subacute inflammation or infection of the anterior chamber of the eye may be induced or exaggerated by wearing contact lenses or use of contact lens products, including the lens case. Eye problems, including corneal ulcers, can develop if the lenses absorb this dye and become discolored. Whenever fluorescein is used in the anterior chamber, the individual and should be considered when selecting the most appropriate type of contact lens. Contact lenses absorb UV light, and the continuing ocular health of the patient and lens performance on eye should be monitored. An appropriate lens design and parameters, the eye care professional should be informed of the following problems may occur:

**ADVERSE REACTIONS**

- Eyes stinging, burning, itching (irritation), or other eye pain
- Reduced sharpness of vision (poor visual acuity)
- Immediate reaction to the lenses.
- Reduced vision or loss of vision
- Eye discharge
- Dryness of eyes
- Redness of eyes
- Foreign body sensation
- Blurred vision
- Sensitivity to light
- Change in tolerance to contact lenses
- Allergic reaction
- Adverse reaction
- Eye care professionals should instruct the patient to REMOVE A LENS and use a non-fluorescent topical anesthetic.

**SYMPTOMS**

- Redness of eye
- Sensitivity to light
- Blurred vision
- Light sensitivity
- Foreign body sensation
- Sensitivity to contact lens
- Discard and replace the lenses and contact his or her eye care professional

**SYMPTOMS OF INFECTION**

- Redness of eye
- Sensitivity to light
- Blurred vision
- Light sensitivity
- Foreign body sensation
- Sensitivity to contact lens
- Discard and replace the lenses and contact his or her eye care professional

**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 Biotture® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotture® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of July 2017 (2017-07-28) and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

**DESCRIPTION**

The Bausch + Lomb Biotture® ONEday lens material, Hyal Gel® (nesofilcon A), is a hydrophilic copolymer of 2-hydroxyethylmethacrylate and N-vinyl pyrrolidone and 76% water by weight when immersed in a sterile saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 315nm to 380nm. The lens is tinted blue with Reactive Blue Dye 24B. The physical or optical properties of the lens are:

- Specific Gravity: 1.039
- Refractive Index: 1.474
- Light Transmittance: 10% (mean) - 90% (max) / 0% (UV) to 65% (V) / 0% (UV) to 65% (V) in the transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 315nm to 380nm.

**LENS PARAMETERS AVAILABLE**

In its hydrated state, the Bausch + Lomb Biotture® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotture® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotture® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, when placed on the cornea, acts as a reflecting medium to focuss light rays on the retina. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 315nm to 380nm.

**INDICATIONS**

- The Bausch + Lomb Biotture® ONEday lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-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 in powers ranging from +20.00D to -20.00D.
- The Bausch + Lomb Biotture® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-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 in powers ranging from +20.00D to -20.00D.
- The Bausch + Lomb Biotture® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D.
CONTAINING DARIES (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens when any of the following conditions exist:

• Acute and subacute infection or infection of the anterior chamber of the eye
• Any eye disease, injury or abnormality that affects the cornea, conjunctiva, or iris
• Severe insufficiency of tear secretion (dry eyes)
• Cornea/hyphopyon induced corneal sensitivity
• Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
• Allergenic reactions of ocular surfaces or adhesives (contacting tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
• Any history of 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 of 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 professional’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 daily wear lenses are worn overnight.
• Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.
• If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact their eye care professional.
• Patients should be instructed not to expose their contact lenses to water while wearing them.
• Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If their contact lenses have been submerged in water when swimming in pools, lakes or oceans, the contact lenses should be discarded and replaced with a new pair. Recommendations for wearing lenses during any water activity should be discussed with the patient.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

• Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
• The potential impact of these factors on the patient’s ocular health should be carefully weighed against the patient’s need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care professional.
• Patients who wear contact 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 professionals 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.
• A patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.

• As with any contact lens, follow-up visits are necessary to assure the continued health of the patient’s eyes. The patient should be instructed to return to a recommended follow-up schedule.
• Astigmatic patients should not be fitted with Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses until the determination is made that the eye has healed completely.
• The lenses are prescribed for disposable wear, and are to be disposed of once they are removed from the patient’s eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of trauma, a foreign body, or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
• Eye care professionals should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens /Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens /Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens, 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-based cosmetics are less likely to damage lenses than oil-based products.
• Be certain that before leaving the facility of the eye care professional, 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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses and those prescribed by the eye care professional.
• 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.

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, scratchy area)
• Other discomfort (e.g., watering, tearing) of the eyes
• Unusual eye secretions
• Redness of the eye
• Reduced sharpness of vision (poor visual acuity)
• Blurred vision, rainbows, or halos around objects
• Sensitivity to light (photophobia)
• Dry eyes

If the patient notices any of the above, he or she should be instructed to:

• Immediately remove the lenses.
• If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an epithelial defect, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and discard the lens; then insert them. After rewearing, if the problem continues, the patient should immediately remove the lenses and contact his or her eye care professional.
• If the above symptoms continue after removal of the lens, or upon reinsemination of a lens, or upon insertion of a new lens, the patient should immediately remove the lenses and contact his or her eye care professional or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Astigmatism (Atropine).) A serious condition such as infection, corneal ulcer/abrasion, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial sludging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Astigmatism (Atropine)

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems is 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. If such an 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 ulcers should contact a referred or a referral specialist who has appropriate training for corneal abrasions such as an ophthalmologist or an optometrist. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/bacterial combinations 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 professional 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. 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 Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses, Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding excision, 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 (water eye) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear.

If these symptoms persist, the patient should be instructed to contact his or her eye care professional.

PRACTITIONER FITTING SETS

Lenses must be discarded after single use and must not be used from patient to patient.
4. Criteria of a Well-Fitted Lens

It is advisable for the patient to only drive during optimal driving conditions. During the first several weeks of wear (when adaptation is occurring), symptoms may last for a brief minute or for several weeks. A patient may at first experience some mild blurred vision, dizziness, headaches, •

6. Adaptation

A patient may at first experience some mild blurred vision, dizziness, headaches, •

7. Other Suggestions

The wearing and replacement schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over wear the lenses. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule chosen by the eye care professional should be provided to the patient.

4. To Refine Near Vision

If the patient is wearing two Low Add lenses:

• Refinement 1: Place Bausch + Lomb Biotrue® ONEday for Presbyopia in the non-dominant eye, then wear the Biotrue® ONEday for Presbyopia in the dominant eye. Have the patient wear each combination and assess vision on a near card. The combination that results in the highest vision can be chosen.

• Refinement 2: When the lens is in place, allow the patient to look around the room at both near and distant objects, observe the reactions. As the patient continues to wear the lens in this manner, the patient should be encouraged to report any problems observed to their eye care professional.

If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using the hand held lenses. Adjust contact lens power when vision in satisfactory.

5. Patient Education

All patients do not function equally well with multifocal corrections. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading lenses. Each patient should understand that multifocal contact lenses can create a visual 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 or patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb Biotrue® ONEday (reposition At Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue® ONEday for Aspheric Soft Contact Lenses). Occupational and environmental visual demands should be considered. The patient must have a visual acuity of 20/20 in each eye with monovision contact lenses to wear the lens comfortably.

1. Visual Demand

a. Driving: driving safely

b. Contact lens power.

c. Monovision contact lens wear may not be optimal for such activities as:

2. Driving automobiles (e.g., driving at night) When patients cannot pass their state driver’s license requirements with monovision contact lenses, they should be advised not to drive with this correction, OR may require that additional over- correction be prescribed. The patient should understand that monovision can create a visual 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 visual dominance can be used:

a. Gross 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. 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 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. Compare whether the patient functions best with the near add lens, the near add lens in the right or left eye.

b. Refractive Error Method

For any patient, the near vision is generally best fit to the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

c. Visual Demand Method

Consider the patient’s occupation during the eye selection process to determine the proper near correction requirements. If a patient’s gaze for near tasks is usually in one direction correct the eye on that side for near.

Example: A student whose places copy to the left side of the desk will usually function best with the near lens in the left eye.

2. Special Fitting Considerations

1. Unilateral Lens Correction

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

A presbyopic myopic patient who requires a +1.75 diopter add would have a +1.75 diopter add on the near lens and the other eye left without lenses.

A presbyopic patient requiring a +3.50 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.
3. Initial Lens Evaluation

- Make ocular measurements for initial contact lens parameter selection, and
- Determine whether a patient is a suitable candidate for contact lenses

4. To Refine Distance Vision

If patient is wearing two Low Add lenses:

- Emphasize the benefits of the clear near vision in straight ahead and upward gaze
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than maintain central positioning between the sclera and palpebral conjunctiva.
- Decenter, especially on post-blink.
- Refinement 1:
  - Presbyopia High Add in non-dominant eye.
  - Fit with Bausch + Lomb Biotrue® ONEday for Presbyopia Low Add (Hydrophilic) Contact Lens Patient Information Booklet.

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 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.
- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens / Bausch + Lomb Biotrue® ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens Patient Information Booklet.