

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses 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 distance objects, observe the reactions. Only after these vision tests 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 news print 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.

4. 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 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.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

GENERAL FITTING GUIDELINES

A. Patient Selection

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry, and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

5. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have 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 their state driver's license requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved with 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 clear near vision and straight-ahead and upward gaze with monovision.

C. Initial Power Determination

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. Vertex distance compensation is generally only necessary for refractions \pm 4.00D.

D. Base Curve Selection (Trial Lens Fitting)

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- ACUVUE® OASYS with Transitions™: 8.4 mm/14.0 mm

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink, and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

2. Criteria of a Flat Fitting Lens

A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink, and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid. If the lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released.

E. Final Lens Power

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:	
Diagnostic lens:	-2.00D
Spherical over-refraction:	-0.25D
Final lens power:	-2.25D

Example 2:	
Diagnostic lens:	-2.00D
Spherical over-refraction:	+0.25D
Final lens power:	-1.75D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from www.acuvue.com.

The decision to fit a patient with 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 PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from www.acuvue.com.

PATIENT MANAGEMENT

- Follow the accepted standard of care in fitting and following up with your patient.
- Schedule the appropriate follow-up examination.
- Preferably, at the follow-up visits, lenses should have been worn for at least six hours.

- Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses, which can be found at www.acuvue.com. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DAILY DISPOSABLE).
- Recommend an appropriate cleaning and disinfection system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

MONOVISION FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant amounts of uncorrected astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

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 correction. Monovision contact lens wear may not be optimal for activities such 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 driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g. reading a menu in a dimly lit restaurant, driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision, and straight ahead and upward gaze that monovision contact lenses provide.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each UV absorbing sterile lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose. The plastic package is marked with the following:

- ACUVUE® OASYS with Transitions™: base curve, power, diameter, lot number, and expiration date

B. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting 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 hand-held trial lens equal to +1.00D 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 +1.00D lens over the right or left eye, which is the non-dominant eye.

2. Other Eye Selection Methods

Other methods include the "Refractive Error Method" and the "Visual Demands Method.

Refractive Error Method

For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

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 function best with the near lens on the left eye.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com



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C. Special Fitting Characteristics

1. Unilateral Vision Correction Requirement

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens whereas a bilateral myope would require corrective lenses on both eyes.

Example:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

Note: Unilateral vision correction is not recommended for ACUVUE® OASYS with Transitions™ contact lenses. Having a darkened lens on only one eye may cause disturbances in the patient's ability to accurately judge depth and the motion of objects. It may also create a cosmetic concern. It is recommended that a 0.00D photochromic contact lens be worn on the other eye in this instance.

2. 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.

3. 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 "General Fitting Guidelines" for base curve selection described in this guide.

PACKAGE INSERT & FITTING INSTRUCTION GUIDE



ACUVUE® OASYS Contact Lenses with Transitions™

senofilcon A Soft (hydrophilic) Contact Lenses
with UV Blocker and Photochromic Additive
for Daily Wear Only

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert and Fitting Guide is intended for the Eye Care Professional, but should be made available to patients upon request.

The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.



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

SYMBOLS KEY	
The following symbols may appear on the label or carton:	
SYMBOL	DESCRIPTION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	CE Mark and Identification number of Notified Body
	UK Conformity Assessment Marking and Identification Number of Notified Body
UV BLOCKING	UV Blocking
	Fee Paid for Waste Management
	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

⁴New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-778

Specific Instructions for Use and Warnings:

- Water Activity**

Instruction for Use

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submerged in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

- Soaking and Storing Your Lenses Instruction for Use**

Instruction for Use

Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).

WARNING:

Do not reuse or “top-off” old solution left in the 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.

SYMBOL	DESCRIPTION
	Lens Orientation Incorrect (Lens Inside Out)
	Authorized Representative in the European Community
	Authorized Representative in the United Kingdom
	Contains Hazardous Substances
	Do Not Use if Package is Damaged
	Medical Device Symbol
	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
	Store Away from Direct Sunlight

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

ACUVUE® OASYS with Transitions™ are soft (hydrophilic) contact lenses available as spherical lenses. The lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent, and UV absorbing monomers.

A combination of the benzotriazole UV absorbing monomer and the naphthopyran monomer (photochromic additive) is used to block UV radiation.

The transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

- Discard Date on Multi-Purpose Solution Bottle**

Instruction for Use

– Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking the contact lenses.

– The discard date refers to the time that the patient can safely use the contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

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

– To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

– To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

- Rub and Rinse Time**

Instruction for Use

To adequately disinfect the lenses, the patient should rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution.

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 the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

Additionally, the photochromic additive absorbs visible light in the range from 380 nm to 780 nm to a minimum 84% transmittance in the inactivated (closed) state. The activated (open) state dynamically absorbs visible light dependent on the lens thickness and the level of UV and high energy visible (HEV) radiation to a minimum of 23% transmittance.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Visible Light Transmittance inactivated: 84% minimum
- Visible Light Transmittance activated (calculated): 23% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability (Dk):

VALUE

103 x 10⁻¹¹ (cm²/sec)
(ml O₂/mL x mm Hg) @ 35°C
122 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg) at 35°C

METHOD

Fatt (boundary corrected, edge corrected)
Fatt (boundary corrected, non-edge corrected)

Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

- Lens Case Care**

Instruction for Use

– Empty and 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 the lens case according to the directions provided by the Eye Care Professional or the manufacturer’s labeling that accompanies the case.

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

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 the eye should be carefully monitored by the prescribing Eye Care Professional.

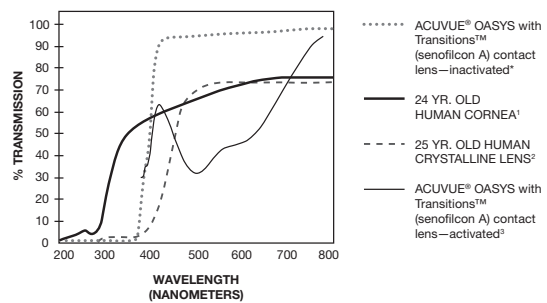
AVAILABLE LENS PARAMETERS

ACUVUE® OASYS with Transitions™ contact lenses are hemispherical shells of the following dimensions:

- Diameter (DIA):** 14.0 mm
- Center Thickness:** 0.085 mm to 0.217 mm (varies with power)
- Base Curve (BC):** 8.4 mm, 8.8 mm
- Powers (D):** -12.00D to +8.00D

TRANSMITTANCE CURVE

ACUVUE® OASYS with Transitions™ contact lens vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



¹The data was obtained from measurements taken through the central 2 mm x 7.5 mm portion for the thinnest marketed lens (-0.25D lens, 0.085 mm center thickness).

¹Leaman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21.

²Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

³The data was obtained from measurements taken through the central 6 mm portion for the thinnest marketed lens (-0.25D lens, 0.085 mm center thickness). The method for measuring the transmittance in the activated state is based on visible range 380 nm to 780 nm utilizing a spectrophotometer and an activation source. Note: There is no impact to the level of UV blocking in the activated state compared to the inactivated state.

- Patients who wear these lenses to correct presbyopia using monovision or multifocal correction 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.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes unless otherwise indicated. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

- Eye Care Professionals should inform the patient that there is no data available on the safety driving performance with ACUVUE® OASYS with Transitions™ contact lenses for individuals age 50 and older who may have lens opacities.

- Eye Care Professionals should instruct the patient to always have a functional pair of spectacles with a current prescription available to use if the patient becomes unable to wear contact lenses, or in circumstances where contact lens wear is not advised.

Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional’s office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- DO NOT** use if the sterile blister package is opened or damaged.
- Always wash, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- DO NOT touch contact lenses with fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

A combination of the benzotriazole UV absorbing monomer and the naphthopyran monomer (photochromic additive) is used to block UV radiation.

The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

The photochromic additive dynamically absorbs visible light allowing for the attenuation of bright light. These lenses absorb visible light in the range from 380 nm to 780 nm to a minimum 84% transmittance in the inactivated (closed) photochromic state and to a minimum of 23% transmittance in the activated (open) photochromic state dependent on the lens thickness and the level of absorbed UV and high energy visible (HEV) radiation.

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

- Carefully follow the handling, insertion, removal, and wearing instructions in the “Patient Instruction Guide” for ACUVUE® OASYS with Transitions contact lenses and those prescribed by the Eye Care Professional.

- Always handle lenses carefully and avoid dropping them.

- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in “Care for a Sticking (Non-Moving) Lens”. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.

- The patient should be advised to never allow anyone else to wear their lenses. Sharing lenses greatly increases the chance of eye infections.

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

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Be aware that wearing a darkened ACUVUE® OASYS with Transitions™ lens on only one eye is not recommended because it may cause disturbances in the patient’s ability to accurately judge depth and the motion of objects. It may also create a cosmetic concern. Therefore, unilateral vision correction is not recommended for ACUVUE® OASYS with Transitions™ contact lenses; it is recommended that a 0.00D photochromic lens be worn on the other eye in this instance.

INDICATIONS (USES)

ACUVUE® OASYS with Transitions™ contact lenses (spherical) are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.

These lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Professionals may prescribe the lenses for frequent/ planned replacement wear with cleaning, disinfection and scheduled replacement (see REPLACEMENT SCHEDULE). When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

When the lenses are worn in a frequent/planned replacement modality, they are intended to be worn for up to 2 weeks (14 days).

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses

- Be aware that ACUVUE® OASYS with Transitions™ contact lenses are not intended for use as protection against artificial light sources, such as sun lamps, lasers, etc.

- Ask the Eye Care Professional about wearing lenses during sporting activities.

- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

Lens Care Precautions:

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.

- Never use solutions recommended for conventional hard contact lenses only.

- Always use fresh, unexpired lens care solutions and lenses. Always follow directions in the package inserts for the use of contact lens solutions.

- Do not change solution without consulting with the Eye Care Professional.

- Sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.

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

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying (e.g. exposing the lens to air for 30 minutes or more) will reduce the ability of the lens surface to return to a wettable state. If the lens surface does become dried out, discard the lens and use a new one.

- Always store worn ACUVUE® OASYS with Transitions™ contact lenses in the lens case and out of direct sunlight.

- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response

- Allergic reactions of ocular surfaces or adhexa that may be induced or exaggerated by wearing contact lenses

- Any active corneal infection (bacterial, fungal, protozoal, or viral)

- If eyes become red or irritated

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF THE PATIENT EXPERIENCES:

- Eye Discomfort,**
- Excessive Tearing,**
- Vision Changes,**
- Loss of Vision,**
- Eye Redness, or**
- Other Eye Problems,**

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.

- Patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.⁴

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

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional 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 the 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.

- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.

- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.

- 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.

- Always store worn ACUVUE® OASYS with Transitions™ contact lenses in the lens case and out of direct sunlight.

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.

- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.