

PROFESSIONAL FITTING AND INFORMATION GUIDE

asmofilcon A (40% water) for 1 Month Replacement Contact Lens

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION

The **asmofilcon A (40% water)** for 1 month replacement contact lens is a hydrophilic contact lens which is available as a spherical, toric, multifocal, and multifocal toric lens. This soft contact lens is indicated for daily wear frequent replacement.

The non-ionic lens material (asmofilcon A) is a random co-polymer containing polydimethylsiloxane macromonomer. It consists of 60% asmofilcon A and 40% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, C.I. Reactive Blue 246.

The hydrophilic material characteristics allow aqueous solutions to enter the lens. In its fully hydrated state, the lens is approximately 40% water by weight.

The lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

asmo filcon A (40% water)	
Spherical Lens Parameters	
Chord Diameter:	14.0 mm
Center Thickness:	0.05 mm to 0.19 mm
Base Curve:	8.30 mm, 8.60 mm
Powers:	+6.00 D to +0.25 D (0.25 D steps) -0.25 D to -6.00 D (0.25 D steps) -6.50 D to -13.00 D (0.50 D steps)
Toric Lens Parameters	
Chord Diameter:	14.0 mm
Center Thickness:	0.05 mm to 0.18 mm
Base Curve:	8.60 mm
Powers:	+6.00 D to -6.00 D (0.25 D steps) -6.50 D to -13.00 D (0.50 D steps)
Cylinder Power:	-0.75 D, -1.25 D, -1.75 D, -2.25 D
Axis:	10° to 180° (10° steps)
Multifocal Lens Parameters	
Chord Diameter:	14.2 mm
Center Thickness:	0.05 mm to 0.19 mm
Base Curve:	8.60 mm
Powers:	+6.00 D to -6.00 D (0.25 D steps) -6.50 D to -13.00 D (0.50 D steps)
Add Power:	+1.00 D (LOW), +2.00 D (HIGH)
Multifocal Toric Lens Parameters	
Chord Diameter:	14.2 mm
Center Thickness:	0.05 mm to 0.09 mm
Base Curve:	8.60 mm
Powers:	0.00 D to -6.00 D (0.25 D steps) -6.50 D to -10.00 D (0.50 D steps)
Cylinder Power:	-0.75 D, -1.25 D, -1.75 D
Axis:	90°, 180°
Add Power:	+1.00 D (LOW)

The physical properties of the lens are:
Refractive Index: 1.423
Light Transmission: 98%
Character: Hydrophilic
Water Content: 40%
Oxygen Permeability at 34-36°C: 129 x 10⁻¹¹ (cm² /sec) (mL O₂)/(mL x mm Hg))

ACTIONS

In its hydrated state, the **asmofilcon A (40% water)** contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS

The **asmofilcon A (40% water)** **SPHERICAL** contact lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic people with disease-free eyes who may have 1.50 diopter (D) or less of astigmatism.

The **asmofilcon A (40% water)** **TORIC** contact lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic people with disease-free eyes with 3.00 diopter (D) or less of refractive astigmatism.

The **asmofilcon A (40% water)** **MULTIFOCAL** contact lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic people with disease-free eyes who may require a reading addition of +3.00 diopter (D) or less and who may have 1.50 diopter (D) or less of astigmatism.

The **asmofilcon A (40% water)** **MULTIFOCAL TORIC** contact lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia with astigmatism) and presbyopia in aphakic and non-aphakic people with disease-free eyes who may require a reading addition of +3.00 diopter (D) or less and who may have 2.50 diopter (D) or less of refractive astigmatism.

The **asmofilcon A (40% water)** contact lens is a frequent replacement lens. The lenses are intended to be worn on a daily wear basis with removal for cleaning and chemical disinfection (not heat) prior to reinsertion, as recommended by the eye care practitioner.

The **asmofilcon A (40% water)** contact lens described in this document is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eye care practitioner based upon your physiological eye condition because individual responses to contact lenses vary. Patients tend to over-wear the lenses initially. The eye care practitioner should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that the **asmofilcon A (40% water)** contact lens is safe to wear during sleep; therefore remove your lenses before sleeping. A normal day of wearing lenses assumes a minimum of 6 hours without wearing lenses per 24-hour period. The optimum individual wearing schedule will vary.

CONTRAINDICATIONS (REASONS NOT TO USE)
DO NOT USE the **asmofilcon A (40% water)** contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa 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 lenses.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- The patient is unable to follow the daily disposable lens care schedule.
- Advise patient not to wear **asmofilcon A (40% water)** contact lens while sleeping.

WARNINGS

Please refer to 'WARNINGS' in the Package Insert.

PRECAUTIONS

Please refer to 'PRECAUTIONS' in the Package Insert.

ADVERSE REACTIONS

Please refer to 'ADVERSE REACTIONS' in the Package Insert.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended wearing schedule of **asmofilcon A (40% water)** contact lens should not be provided with this lens. All necessary precautions and warnings should be discussed and understood by the patient (review Package Insert with the patient).

FITTING PROCEDURE

Pre-fitting Examination:

- A pre-fitting patient history and examination are necessary to:
- Determine whether a patient is a suitable candidate for daily wear contact lenses (see 'CONTRAINDICATIONS').
 - Collect and record baseline clinical information to which post-fitting examination results can be compared.
 - Make ocular measurements for initial contact lens parameter selection.

1. Initial Lens Power Selection

Spherical Lens Power:

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- Select an appropriate power lens and place the lens on the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium.

Toric Lens Power:

- Lens power is determined from the patient's best spherical-cylindrical refraction. Select a spherical power based on the refraction with vertex compensation and select a cylindrical power using the same compensation for meridional power.
- Select an appropriate trial lens and place the lens on the eye making the scribe dot line to be at the inferior position of the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium.

Multifocal Lens Power:

- Distance lens spherical power is determined the same as a spherical lens described above. Refer to the add power prescribed for the patient's glasses for the initial add selection.

Multifocal Toric Lens Power:

- Distance lens spherical power is determined the same as a spherical lens described above. Refer to the add power prescribed for the patient's glasses for the initial add selection.
- The lens power is determined from the patient's best spherical-cylindrical refraction. Select a spherical power based on the refraction with vertex compensation, and select a cylindrical power using the same compensation for meridional power.

2. Initial Lens Evaluation

- Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.
- To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
 - Position/Centration: The lens should provide full corneal coverage.
 - Movement/Stability: The lens should provide discernible movement with:
 - Primary gaze blink
 - Upward gaze blink
 - Upward gaze lag
 - Toric Lens Rotation: There is a scribe-mark that should rotate to approximately the 6:00 o'clock position when pulling down the lower eyelid during the slit lamp examination. Careful examination during the blink cycle should note the mid-blink resting location, the amount and direction of rotation during the blink and the time between blinks that it takes for the lens to return to its resting position. Remember, each hour of rotation on the clock is 30 degree shift in axis.

3. Final Power Determination

- Spherical Power Determination: Spherical over refraction to the best corrected visual acuity.
- Toric Power Determination: Spherical-Cylindrical over refraction to determine additional sphere or cylinder needed for best corrected visual acuity. Off axis location noted during the lens position/movement and stability evaluation may require ordering a lens with the cylindrical axis that compensates for the off axis rotation. When determining the amount of cylinder for a lens that exhibits moderate inter-blink movement, the

practitioner may consider reducing the cylindrical correction and ordering a partial spherical equivalent power to reduce visual acuity fluctuation between blinks.

- Multifocal Power Determination: Examine the distance, intermediate and near vision binocularly and monocularly. Make adjustments in power if necessary.
- Multifocal Toric Lens Power Determination: Examine the distance, intermediate and near vision binocularly and monocularly. Make adjustments in power if necessary. Spherical-Cylindrical over refraction to determine additional sphere or cylinder needed for best corrected visual acuity. Off axis location noted during the lens position/movement and stability evaluation may require ordering a lens with the cylindrical axis that compensates for the off axis rotation. When determining the amount of cylinder for a lens that exhibits moderate inter-blink movement, the practitioner may consider reducing the cylindrical correction and ordering a partial spherical equivalent power to reduce visual acuity fluctuation between blinks.

4. Specific Instructions for Presbyopic Patients

- Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal or multifocal toric contact lenses. The following information and instructions have proven useful in advising patients who wear **asmofilcon A (40% water)** Multifocal or Multifocal Toric contact lenses.
 - A contact lens that contains different powers for distance and near visual acuity involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves with the eye, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding where to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with glasses.
 - Although many individuals use **asmofilcon A (40% water)** Multifocal or Multifocal Toric contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear glasses, or where the disadvantages associated with glasses are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.
 - Situations where vision with multifocal or multifocal toric contact lenses may be less sharp or otherwise "different" than what is experienced with glasses often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). **Patients should be instructed to make use of good light when reading fine print.**
 - Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery under these conditions until they gain some experience with the lenses in a similar visual environment.
 - Small changes in lens power can often make an enormous difference in the quality of the vision experienced with multifocal or multifocal toric contact lenses. Such changes can be best tailored to individual needs only after the lenses have been worn during the tasks and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved is important for patient motivation during the initial period of lens wear.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.25 mm, lags downward about 1.0 to 1.5 mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements. After the trial lens has settled on the eye (10-20 minutes), manipulate the lens using eyelid pressure and observe for indications of excessive tightness. The lens should move freely and easily under the slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1.0 to 1.5 mm. Rotation of the lens while blinking should be adequate to demonstrate adequate movement but stable enough to maintain vision.

2. Characteristics of a Tight (Steep) Lens

A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens

A loose (flat) lens sags more than 2.0 mm on upward gaze.

FOLLOW-UP CARE

- Follow-up examinations are recommended by the eye care practitioner. They are necessary to ensure continued successful contact lens wear.
- Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- After the lens has been removed, conduct a thorough bio-microscopy examination.
 - The presence of vertical corneal striate in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions.

If the **Criteria of a Well-Fitted Lens** are not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

FOLLOW-UP EXAMINATIONS

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six month period of lens wear

MONOVISION FITTING GUIDELINES

1. Patient Selection

Monovision Needs Assessment:

- For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. Both the **asmofilcon A (40% water)** Spherical and Toric contact lenses are appropriate for this correction modality. The amblyopic patient may not be a good candidate for monovision with the **asmofilcon A (40% water)** contact lens designs.
- 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. Wearing monovision contact lenses may not be optimal for such activities as:

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities
- 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 bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

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

Ocular Preference Determination Methods:

Method 1: Determine which eye is the "sight 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 latest reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

Refractive Error Method:

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

Visual Demands Method:

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

3. Special Fitting Consideration

Unilateral Lens Correction:

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

Example:

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

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

4. Near Add Determination

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

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines described earlier in the guide.

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

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or their 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 tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions has been completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted. An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

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

7. Other Suggestions

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental glasses to wear over monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

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

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

The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the **asmofilcon A (40% water)** contact lens Patient Instructions.

LENS HANDLING (in-office cleaning)

Wash and rinse hands thoroughly, making certain that all soap residues have been rinsed away before drying with a lint-free towel. It is suggested to wet the lens while in the eye using rewetting drops before removal. Always start with the right eye first in order to avoid mixing the lenses. When handling the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

asmofilcon A (40% water) contact lens is not reused in diagnostic procedures.

CLEANING

The Eye Care Practitioner should review with the patient, lens care directions for cleaning, disinfecting and storing, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to have replacement lenses or back-up glasses available at all time.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to over-wear the lenses initially. It is important not to exceed the wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important. The maximum suggested wearing schedule for the **asmofilcon A (40% water)** contact lens is suggested below.

DAY	1	2	3	4	5	6 and after
HOURS	6	8	10	12	14	All waking hours

STUDIES HAVE NOT BEEN CONDUCTED TO SHOW THAT THE **"asmofilcon A (40% water)** contact lens" IS SAFE TO WEAR DURING SLEEP.

REPLACEMENT SCHEDULE

The Eye Care Practitioner should determine the wearing and replacement schedule, based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving or cannot be removed), you should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly onto the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues for more than 15 minutes, you should immediately consult the Eye Care Practitioner.

REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **asmofilcon A (40% water)** contact lens within 5 days to the address below.

Additional Package Inserts, Professional Fitting and Information Guides, and Patient Instructions are available from:

Menicon America, Inc.
North Billerica, MA 01862
1-800-MENICON (1-800-636-4266)
information@menicon.com

HOW SUPPLIED

Each lens is supplied sterile, in a lens blister pack, containing buffered saline solution. Each container is marked with base curve, dioptic power, diameter, Rx Symbol, Sterile Symbol, composition of the lens, manufacturing lot number and expiration date of the lens.

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