

PACKAGE INSERT

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.

IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to the patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lens.

DESCRIPTION

The **asmofilcon A (40% water)** for 1 month replacement contact lens is a hydrophilic contact lens which is available as a spherical, toric, and multifocal 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:

asmofilcon A (40% water)	
Spherical Lens Parameters	
Chord Diameter:	14.0 mm
Center Thickness:	0.05 mm to 0.19 mm
Base Curve:	8.30 to 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)
Toric Lens Parameters	
Chord Diameter:	14.0 mm
Center Thickness:	0.05 mm to 0.18 mm
Base Curve:	8.60 mm
Powers:	0.00 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
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)

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)** 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.

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 lens wearing and lens care regimen or is unable to obtain assistance to do so.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that you follow the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

You should be advised of the following instructions for use and warnings pertaining to contact lens wear:

i. Soaking and Storing the Lenses

Instruction for Use:

Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) the lenses.

Warnings:

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.

ii. Rub and Rinse Time

Instruction for Use:

- Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution to adequately disinfect the lenses.

Warnings:

- Rub and rinse the 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.

iii. Lens Case Care

Instruction for Use:

- Empty and clean contact lens cases by rubbing with clean fingers using fresh, sterile disinfecting solutions/contact cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with a 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 dry.
- Replace the lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

Warnings:

Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to not contaminate the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

iv. Water Activity

Instruction for Use:

- Do not expose the contact lenses to water while wearing them.

Warnings:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

v. 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 to 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.

Warnings:

Using the 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 the tip of the container to any surface. Replace the cap after use.
- To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE FOLLOWING IS EXPERIENCED:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Eye Redness,
- Or Other Eye Problems.

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PRACTITIONER.

- Daily wear lenses are not indicated for overnight wear, and you should not wear lenses while sleeping. Clinical studies have shown that risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.
- You should be cautioned that proper use and care of the contact lenses and lens care products, including lens cases, are essential for the safe use of these products. It is essential that you follow your Eye Care Practitioner’s directions and all labeling instructions for proper use of lenses and lens care products. You should fill the lens case with fresh solution every time you store your lenses, and never re-use solution. Additionally, you should clean and rinse your lens case between uses as recommended by your Eye Care Practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

The results of a study¹ indicate the following:

- The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 people and about 20.9 per 10,000 people in extended wear contact lens users.
- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.
- When daily users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following the directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Practitioner. It is recommended that contact lens wearers see their Eye Care Practitioner routinely as directed.

1 New England Journal of Medicine, September 21, 1989;321(12), pp.773-783

PRECAUTIONS

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Never use solutions recommended for conventional hard contact lenses only.
- Always follow the directions in the package inserts for the use of contact lens solutions.
- Always use a chemical lens care system. Use of heat care system can damage the contact lenses.

- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should **immediately** consult your Eye Care Practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, 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.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Always handle lenses gently and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions in the Patient Instructions for **asmofilcon A (40% water)** contact lenses and those prescribed by the Eye Care practitioner.
- Never wear lenses beyond the period recommended by the Eye Care Practitioner.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hairspray are used while wearing the lenses, exercise caution and keep your eyes closed until the spray has settled.
- Ask the Eye Care Practitioner about wearing the lenses during sporting activities.
- Keep water away from your contact lenses. Avoid showering in contact lenses and remove them before using a hot tub or swimming.
- Inform the doctor (Health Care Practitioner) about being a contact lens wearer.
- Always contact the Eye Care Practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
- DO NOT use the contact lenses if the sterile package has been opened or damaged, or the expiration date has been passed.
- Look closely at the contact lenses before wearing them and DO NOT wear them if they are in any way damaged.
- Store the contact lenses at room temperature. Do not allow the lenses to freeze.
- You should have replacement contact lenses or glasses available at all times.

ADVERSE REACTIONS

The following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Less comfort than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.

- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

If you notice any of the above, immediately remove your lens.

- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, **DO NOT PUT THE LENS BACK ON THE EYE**. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect both lenses; then reinsert them.
- After reinsertion, if the problem continues you should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONER**.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. KEEP THE LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional contact lens fitting methods apply to **asmofilcon A (40% water)** contact lens. For a detailed description of the fitting techniques, refer to the Professional Fitting and Information Guide for **asmofilcon A (40% water)** contact lens. The copies are available from:

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

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

The **asmofilcon A (40% water)** contact lens is indicated for daily wear. The suggested maximum wearing time for the contact lenses is:

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.

LENS CARE DIRECTIONS

Eye Care Practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

- 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. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.

General Lens Care (For Planned Replacement):

Basic Instructions:

- Always use **fresh, unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow the instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems **unless indicated on solution labeling**.

- Lenses should be cleaned, rinsed, and disinfected each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme cleaner is not recommended.
- The eye care practitioner should recommend a care system that is appropriate for **asmofilcon A (40% water)** contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow the directions.
- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- **After cleaning**, and rinsing, **disinfect** lenses using the system recommended by the manufacturer and/or Eye Care Practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the package insert or the eye care practitioner for information on the storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Practitioner.
- Eye Care Practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide)

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning** and rinsing, to **disinfect**, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the Eye Care Practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before** wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- When using hydrogen peroxide lens care systems, you must **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye.
- Follow the recommendations on the hydrogen peroxide system labeling exclusively. After disinfecting with a peroxide system, the lenses should be rinsed with sterile saline.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put them on the eyes.

Cautions:

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

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the Eye Care Practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **asmofilcon A (40% water)** contact lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

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.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

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

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.

Print Date: 2018-05-01
RDASRBPI001