

## PACKAGE INSERT

### hioxifilcon A (57% water) for Daily Disposable Soft Contact Lens

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

#### IMPORTANT

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

#### DESCRIPTION

The **hioxifilcon A (57% water)** for daily disposable soft contact lens is available as a single vision spherical or toric design.

The **hioxifilcon A (57% water)** contact lens packaging system is designed to reduce lens handling by always presenting the lens ‘convex’ side up upon opening, which ensures correct lens orientation for proper eye insertion. The approximately 1 mm flat pack packaging system can be easily opened and reinforces the single-use factor.

The non-ionic lens material (hioxifilcon A) is a random co-polymer of 2-hydroxyethyl methacrylate and glycerol methacrylate cross-linked with ethylene glycol dimethacrylate. It consists of 43% hioxifilcon A and 57% water by weight when immersed in a buffered saline solution. The contact lenses are available with a pale blue visibility handling tint, color additive ‘Reactive Blue #19’ 21CFR Part 73.3121.

The hydrophilic material characteristics allow aqueous solutions to enter the contact lenses. In its fully hydrated state, the contact lenses are approximately 57% water by weight.

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

<b>hioxifilcon A (57% water)</b>	
<b>Spherical Contact Lens</b>	
Diameter	14.2 mm
Center Thickness	0.10 mm to 0.20 mm
Base Curve	8.4 mm, 8.6 mm
Powers	+4.00 to +0.50 D (0.25 D steps) -0.50 to -6.00 D (0.25 D steps) -6.50 to -10.00 D (0.50 D steps)
<b>Toric Contact Lens</b>	
Diameter	14.5 mm
Center Thickness	0.10 mm to 0.18 mm
Base Curve	8.6 mm
Powers	+2.00 to -6.00 D (0.25 D steps) -6.50 to -10.00 D (0.50 D steps)
Cylinder Power	-0.75 D, -1.25 D, -1.75 D
Axis	15°, 90°, 165°, 180°
Lens Design	Peri Ballast and Prism Ballast

The physical properties of the contact lenses are:

**Refractive Index: 1.409**

**Surface Character: Hydrophilic**

**Light Transmittance: 99%**

**Water Content: 57%**

**Oxygen Permeability: 25.38 x 10<sup>-11</sup> (cm<sup>2</sup>/sec) (mL O<sub>2</sub>/(mL x mm Hg))**

#### ACTIONS

The **hioxifilcon A (57% water)** contact lens, when put on the cornea, acts as a refracting medium to focus light rays on the retina.

#### INDICATIONS

The **hioxifilcon A (57% water)** spherical and toric contact lenses are intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with new lenses. The contact lenses are not intended to be cleaned or

disinfected, and should be discarded after a single use.

The **hioxifilcon A (57% water)** contact lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eye care professional or practitioner based upon patient’s physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the contact lenses initially. The eye care professional or practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that **hioxifilcon A (57% water)** contact lens is safe to wear during sleep; therefore, remove the contact lenses before sleep. Normal daily wear of the contact lenses assumes a minimum of 6 hours non-lens wear per 24-hour period. Optimum individual wearing schedule will vary.

The **hioxifilcon A (57% water)** spherical contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic disease-free eyes of people who may have 1.00 diopter (D) or less of astigmatism that does not interfere with visual acuity.

The **hioxifilcon A (57% water) Toric** contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic disease-free eyes of people who may have 3.00 diopter (D) or less of astigmatism.

#### CONTRAINDICATIONS

DO NOT USE the **hioxifilcon A (57% water)** contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment 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 surrounding tissues that may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions
- Any active corneal infection
- If eyes become red or irritated
- Incomplete corneal healing following eye surgery
- The patient is unable to follow the lens wearing schedule or unable to obtain assistance to do so.

#### WARNINGS

Patients should be advised of the following warnings pertaining to wearing contact lenses:

- Problems with contact lenses could result in **serious injury** to the eyes. It is essential that patients follow the directions of the eye care professional or practitioner and all instructions on the labels for proper use of contact lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear contact lenses are not intended for overnight wear, and patients should be instructed not to wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions increases when daily wear contact lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when contact lenses are worn overnight or while sleeping.<sup>1,2</sup>
- Do not expose the contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If contact

lenses have been submersed in water such as when swimming in pools, lakes or oceans, discard the contact lenses and replace with new lenses. Ask the eye care professional or practitioner for recommendations about wearing contact lenses during any activity involving water.

- 1 CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37
- 2 New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

#### PRECAUTIONS

- DO NOT use the contact lenses if the sterile package has been opened or damaged, or the expiration date has passed.
- Examine the contact lenses to be sure that they are free of any damage or foreign bodies. DO NOT put in the contact lenses if they are in any way damaged.
- Store the contact lenses at room temperature. Do not allow the lenses to freeze.
- If the contact lenses stick (stop moving) on the eyes, follow the recommended directions on “CARE FOR A STICKING (NON-MOVING) LENS”. The contact lenses should move freely on the eyes for the continued health of the eyes. If non-movement of the contact lenses continue, the patient should immediately consult the eye care professional or practitioner.
- No cleaning or disinfecting is necessary for the daily disposable contact lenses. Always discard the used contact lenses. Have replacement contact lenses or glasses ready in case of need to remove the lenses during the day.
- Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on contact lenses. It is best to put on contact lenses before putting on makeup. Water-based cosmetics are less likely to damage contact lenses than oil-based products.
- Handle the contact lenses with care (be careful not to drop them).
- 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.
- Do not touch the contact lenses with fingernails.
- Never use tweezers or other tools to remove the contact lenses from the lens container unless specifically indicated for that use. Pour the lens into a hand.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for **hioxifilcon A (57% water)** contact lens and those prescribed by the eye care professional or practitioner.
- Never wear the contact lenses beyond the period recommended by the eye care professional or practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing the contact lenses.
- If aerosol products such as hairspray are used while wearing the contact lenses, exercise caution and keep the eyes closed until the spray has settled.
- Consult the eye care professional or practitioner for instructions on wearing the contact lenses during sports or water activities, or for specific occupations.
- Keep water away from the contact lenses. Avoid showering in contact lenses and remove them before using a hot tub or swimming.
- Inform the medical doctor of being a contact lens wearer.
- Consult the eye care professional or practitioner before using any medicine in the eyes.
- Inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require not to wear contact lenses.

- Follow-up visits are necessary to assure the continued health of the eyes.

#### ADVERSE REACTIONS

- Eye stinging, burning, itching, or any other pain in the eyes
- Less comfort than when the contact lenses were first put in the eyes
- Continuous foreign body or scratching sensation
- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, rainbows, halos, photophobia, or dry eyes

If any of the above problems occur, the patient should be instructed to:

- **Immediately remove the contact lenses.**
- If the discomfort or problem stops, look closely at the contact lenses. If the contact lenses are in any way damaged, do not put them back in the eyes. Discard the contact lenses and replace with new lenses. If the problem continues after putting in new contact lenses, the patient should **immediately remove the contact lenses and consult the eye care professional or practitioner.**

If the above symptoms continue after removal of the contact lenses or upon putting in new contact lenses, the patient should immediately remove the contact lenses and consult the eye care professional or practitioner, or physician, who must determine the need for examination, treatment or referral without delay. A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

#### PUTTING IN THE CONTACT LENSES

Conventional methods of putting in contact lenses for regular corneas apply to the **hioxifilcon A (57% water)** contact lens. For a detailed description of the methods, refer to the **hioxifilcon A (57% water)** Professional Fitting and Information Guide which is available from:

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

#### WEARING SCHEDULE

#### THE WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL OR PRACTITIONER.

The **hioxifilcon A (57% water)** contact lens is indicated for single use 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 “**hioxifilcon A (57% water)** contact lens” IS SAFE TO WEAR DURING SLEEP.

#### REPLACEMENT SCHEDULE

The **hioxifilcon A (57% water)** contact lens is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with new lenses.

#### LENS CARE DIRECTIONS

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

**CARE FOR A STICKING (NON-MOVING) LENS**

If the contact lenses stick (stop moving) on the eyes, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eyes and wait until the lenses begin to move freely on the eyes before removing them. If non-movement of the contact lenses continue for more than 10 minutes, the patient should **immediately** consult the eye care professional or practitioner.

**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 THE EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE THE CONTACT LENSES PROMPTLY. CONSULT THE EYE CARE PROFESSIONAL OR PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**HOW SUPPLIED**

The sterile **hioxifilcon A (57% water)** contact lens is shipped immersed in buffered saline solution in a non-traditional packaging system, the Flat Pack which is marked with the information for base curve, dioptric power, diameter, Single Patient Use, Rx Symbol, Sterile Symbol, composition of the lens, manufacturing lot number and expiration date of the lens.

**REPORTING OF ADVERSE REACTIONS**

All serious adverse experiences and reactions observed in patients wearing the **hioxifilcon A (57% water)** contact lens should be reported to:

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

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