

PACKAGE INSERT

FOR

Hioxifilcon A SOFT CONTACT LENS FOR DAILY WEAR

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION

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

DESCRIPTION

The Hioxifilcon A spherical and toric visibly tinted soft contact lens is a hemispherical shell with the following parameters:

PARAMETER	VALUE
Diameter:	12.5 mm to 16.5mm
Center Thickness:	Varies with power (0.15mm at -3.00D)
Base Curve:	6.0 to 10.0 in 0.1mm steps
Sphere Power Range:	-20.0D to +20.0D in 0.1D steps
Cylinder Power Range:	-0.25 to -8.00 in 0.1D steps
Axis:	0° to 360° in 1° steps
Prism:	1.20 to 1.50

The non-ionic lens material, Hioxifilcon A, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 41% hioxifilcon A and 59% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perfluorooctanesulfonate. The lens is available in clear and with a blue visibility-handling tint, phthalocyanato (2) - (copper).

The physical properties of the lenses are:

PROPERTY	VALUE
Refractive Index	1.515 (dry); 1.404 (hydrated)
Light Transmission	greater than 95%
Water Content	59%
Specific Gravity	1.308 (dry); 1.136 (hydrated)
Oxygen Permeability (Dk Value)	20×10^{-11} Fatt Units (cm^2/sec)(ml O ₂ /ml x mm Hg @ 35°C), revised Fatt method

ACTIONS

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

CAUTION

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 were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner 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 must 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 practitioner.

INDICATIONS

Hioxifilcon A soft spherical contact lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and astigmatism of up to 0.75 diopters or less that does not interfere with visual acuity. Hioxifilcon A soft toric lenses are indicated for the correction of astigmatism of 5.00 diopters or less. Lenses are available in clear and with blue visibility tint.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using either a heat or chemical disinfection system.

CONTRAINDICATIONS

DO NOT USE the Hioxifilcon A soft contact lenses when any of the following conditions are present:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctive, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-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 solution, which is to be used to care for Extreme-D soft contact lenses.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

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

PROBLEMS WITH CONTACT LENSES AND CONTACT LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products, including the lens care solutions. *SEVERE EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE ANY DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.*

Daily Wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.

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

If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lens and promptly contact his or her eye care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

PRECAUTIONS

Follow the instruction below to prevent damage to your eye(s) or to the lens(s):

- Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon A are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner 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 practitioner.
- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorbs 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. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lens or should have someone else available who can remove the lens for him or her.
- Eye care practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use FRESH, STERILE, UNEXPIRED lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or rewetting lenses. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions in Care for a Dried-Out Dehydrated Dry Lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in Care for Sticking Non-Moving Lenses. 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 **IMMEDIATELY** consult his or her eye care practitioner.
- Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing, and wearing instructions in the patient instructions for the Hioxifilcon A soft contact lens and those prescribed by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine or medications 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 the patient not wear contact lenses.
- 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.

ADVERSE REACTIONS

The following adverse effects have been recognized as potential problems with the use of soft contact lenses:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed in the eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- Unusual eye secretions
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Sensitivity to light (photophobia).
- Dry eyes

If you notice any of the above, **IMMEDIATELY REMOVE LENS**.

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE**. Place the lens in the storage case and contact your 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, thoroughly clean, rinse, and disinfect the lens then reinsert it.
- After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS AND CONSULT THE EYE CARE PRACTITIONER**.
- If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. **SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.
- As with any contact lens, corneal thickening and abrasions may occur if the lens does not fit properly or if wearing time is excessive. Conventional methods of fitting contact lenses apply to Hioxifilcon A soft contact lenses. For a detailed description of the fitting techniques, refer to the Professional Fitting Guide.

WEARING SCHEDULE

The eye care practitioner should determine the wearing and replacement schedule. Patients tend to over-wear the lenses initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important.

recommends that the lenses be discarded and replaced with new lenses every two weeks. However, the eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

Hioxifilcon A soft contact lenses are indicated for daily wear. The maximum suggested wearing schedule for Hioxifilcon A soft contact lenses is as follows.

SUGGESTED WEARING SCHEDULE

Days	Continuous Hours	Days	Continuous Hours
1	3	8	8
2	3	9	8
3	4	10	10
4	4	11	12
5	6	12	14
6	6	13	15
7	8	14 and after	All waking hrs

Studies have not been completed to show that Hioxifilcon A soft contact lenses are safe to wear during sleep

LENS CARE DIRECTIONS

Use the lens care system recommended by your eye care practitioner. Always wash and rinse your hands before handling your contact lenses.

- **Basic Instructions:**

Care of contact lenses takes very little time and involves **THREE** essential steps -**CLEANING, RINSING, AND DISINFECTING**. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse, and dry hands before handling contact lenses. Always use **FRESH, STERILE, UNEXPIRED** lens care solutions. Use the recommended lens care system; either chemical (no heat) or heat (thermal). Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING**. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in your mouth. 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.

The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfecting solution prior to disinfecting the lens. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

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 instructions.

- **Lens cleaning, disinfection, and storage:**

Clean one lens first (always the same lens first to avoid mix-ups) **rinse** the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, **disinfect** lens using the system recommended by the manufacturer and/or the eye care practitioner. To store lenses, disinfect and leave them in the close/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of the lenses.

- **Lens Case Cleaning and Maintenance:**

Contact lens cases can be a source of bacteria growth. After removing the lens from the 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 case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the Hioxifilcon A soft contact lens. Failure to follow this procedure may result in development of serious ocular infections.

- **Care for a dried out (dehydrated) dry lens:**

If for some reason, your lens dries out completely, a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures – including soaking the lens in storage and disinfection solution for four hours before wearing again.

- **Care for a sticking (non-moving) lens:**

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 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 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

- **Storage:**

Hioxifilcon A soft contact lenses must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lenses.

- **Chemical (NOT HEAT) Lens Disinfection:**

1. Wash and rinse your hands thoroughly **BEFORE HANDLING LENS**.
2. After removal of lens, **CLEAN** the lens by applying three drops of cleaner to each surface. Place the lens on open palm and gently rub with one finger for 20 seconds.
3. **AFTER CLEANING**, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells for a minimum of 4 hours.

Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.**

Caution: 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 rinsing solution prior to placement on the eye should reduce the potential for irritation.

- **Heat (THERMAL) Lens Disinfection:**

1. Wash and rinse your hands thoroughly **BEFORE HANDLING LENS**.
2. After removal of the lens, **CLEAN** the lens by applying three drops of cleaner to each surface. Place the lens on open palm and gently rub with one finger for 20 seconds.
3. **AFTER CLEANING**, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. After you clean and thoroughly rinse your contact lens, prepare the empty lens storage case. Use a solution recommended by your eye care practitioner to keep the lens wet during disinfection.
5. Wet the lens chambers (sections) with the solution recommended by your eye care practitioner.
6. Place each lens in the correct chamber of the lens storage case.
7. Fill the chamber with the recommended solution. Completely cover the lens.
8. Tightly close both chambers of the lens storage case.
9. Put lens case in heat disinfecting unit and follow the directions included with unit to run heat cycle.
10. Do not handle lens case until it has cooled sufficiently to touch.
11. Leave the lenses undisturbed in closed lens case until ready to put on eyes. If longer than one week the lenses should be recycled through the cleaning/disinfecting process.
12. Before reinsertion of the lenses, no rinsing is necessary unless recommended by your eye care practitioner.

EMERGENCY (ALTERNATE) METHOD FOR HEAT (THERMAL) DISINFECTING

If your heat-disinfecting unit is not available, place tightly closed lens storage case, which contains the lenses, into pan of already boiling water. Leave closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow to cool for 30 minutes to complete the disinfecting of the lenses.

NOTE: USE OF THE HEAT DISINFECTING UNIT SHOULD BE RESUMED AS SOON AS POSSIBLE.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS

Commercial solutions from Allergan, CIBA, Alcon etc. are all compatible with Hioxifilcon A. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows recommended solutions that were used for the FDA study.

Daily Cleaner:	Alcon Opti-Free Daily Cleaner
Rinsing Solution:	Alcon Saline for Sensitive Eyes; Alcon Unisol
Disinfecting Solution:	Alcon Opti-Free (Rinse-Store and Disinfection Solution) for Soft Hydrophilic Lenses; Alcon Unisol Solutions
Lubricant/Rewetting Drops:	Alcon Opti-Free Rewetting Drops
Enzymatic Cleaner:	Alcon Optizyme Enzymatic Cleaner

HOW SUPPLIED

Each Hioxifilcon A soft contact lens is supplied sterile in a glass vial containing buffered normal saline solution. The glass vial is labeled with the lens parameters, unique identification number, and the expiry date of the lens.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Hioxifilcon A soft contact lenses should be reported to:

SpecialEyes LLC
PO Box 21417
Bradenton, FL 34204-1417 USA

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