

PACKAGE INSERT

BAUSCH + LOMB

NOVAKONE®

Soft Contact Lenses for Keratoconus

NOVAKONE® (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

NOVAKONE SPHERICAL

Catalog No. **AONKS**

(hioxifilcon D - 54%)

NOVAKONE TORIC

Catalog No. **AONKT**

(hioxifilcon D - 54%)

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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.

DESCRIPTION

NOVAKONE SOFT CONTACT LENSES are available in the hioxifilcon D material.

NOVAKONE SPHERICAL lenses are manufactured with a spherical front surface for the correction of visual acuity in persons requiring keratoconus management who are myopic or hyperopic. NOVAKONE SPHERICAL lenses are available clear or with a blue visibility-handling tint, [phthalocyaninato (2-)] copper.

NOVAKONE TORIC lenses have a toric anterior or posterior surface generated for the purpose of correcting vision in persons requiring keratoconus management and who possess astigmatism. NOVAKONE TORIC lenses are designed with dynamic stabilization or thin zones for orientation. NOVAKONE TORIC lenses are available clear or with a blue visibility-handling tint, [phthalocyaninato (2-)] copper.

NOVAKONE SOFT CONTACT LENSES are flexible hemispherical shells of the following dimensions:

- Chord Diameter: 10.0 mm to 16.0 mm
- Optical Zone Diameter: 6.0 mm to 8.5 mm
- Center Thickness: 0.35 mm standard
- Center Base Curve: 5.4 mm to 8.6 mm
- Fitting Curve: 8.3 mm to 8.9 mm
- Spherical Powers (toric lenses): -30.00 D to +30.00 D
- Spherical Powers (spherical lenses): -30.00 D to +30.00 D
- Cylinder Powers (toric lenses): -0.50 D to -10.00 D
- Axis (toric lenses): 1° to 180°

The NOVAKONE (hioxifilcon D) Soft Contact Lens is manufactured from a non-ionic lens materials made from a co-polymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA). The NOVAKONE (hioxifilcon D) Soft Contact Lens consists of 46% hioxifilcon D and 54% water by weight when immersed in buffered normal saline.

The physical/optical properties of the lenses are:

	(hioxifilcon D)
Refractive Index	1.510 (dry) / 1.408 (hydrated)
Light Transmittance	> 95%
Water Content	54%
Specific Gravity	1.300 (dry) / 1.136 (hydrated)
Oxygen Permeability	21

ACTIONS

When placed on the cornea, the NOVAKONE (hioxifilcon D) Soft Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS

The NOVAKONE SPHERICAL lens is indicated for daily wear for persons requiring keratoconus management for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not aphakic persons with otherwise non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

The NOVAKONE TORIC lens is indicated for daily wear for persons requiring keratoconus management for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with otherwise non-diseased eyes and who possess refractive astigmatism not exceeding 10 diopters.

The lenses are available in either conventional or planned replacement modalities.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the NOVAKONE Soft Contact Lenses when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality (other than keratoconus) that affects the cornea, conjunctiva, 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 a solution which is to be used to care for NOVAKONE Soft Contact Lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- Patient is 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 lens care products could result in serious injury to the eye.** It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- 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 daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon D 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 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.
- Aphakic patients should not be fitted with NOVAKONE Soft Contact Lenses until the determination is made that the eye has healed completely.
- Patients who have had radial keratotomy (RK) may be more prone to new vessel growth along incision lines. More frequent follow-up care may be required to ensure that any neovascularization is detected at an early stage. Patients should be discontinued from lens wear if new vessel growth starts to approach the pupillary zone.
- 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. 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. Wait at least one hour before replacing the lens. Too early replacement may allow the lenses 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.

Eye care practitioners should carefully instruct patients about the following lens care regimen and safety precautions:

- 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.
- Always use **fresh, unexpired** lens care solutions.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use **only chemical (not heat) lens care systems** labeled for use with soft contact lenses.
- 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.
- Tap water, distilled water, or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions in **CARE FOR A DRIED OUT (DEHYDRATED) LENS** if the lens surface becomes dried out.
- 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.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, 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 contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for the NOVAKONE (hioxifilcon D) and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- Contact lenses should never be shared between users.
- If aerosol products such as hair spray are used while wearing the 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 and water-related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis.
- Inform the 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 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 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.
- 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 do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when the lens was first placed on the eye
- Abnormal feeling of something in the eye (foreign body, 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 the patient notices any of the above, he or she should be instructed to:

- **Immediately remove the lenses.**
- 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 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, the patient should thoroughly clean, rinse, and disinfect the lens; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner**.

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care practitioner** or physician, who must determine the need for examination, treatment, or referral without delay. (See Important Treatment Information for Adverse Reactions.) 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 staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or a steroid/antibiotic combination may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately, and the lens and lens care products retained for analysis and culturing.

FITTING

Conventional methods of fitting contact lenses do apply to NOVAKONE (hioxifilcon D) Soft Contact Lenses. For a detailed description of the fitting techniques, refer to the Professional Fitting Guide, copies of which are available from: Bausch & Lomb Incorporated, 6 Lancaster Pkwy, Lancaster, NY 14086 USA; Telephone: 1-800-253-3669.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to overwear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Frequent/Planned Replacement Wear

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE NOVAKONE (HIOXIFILCON D) SOFT CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

HANDLING OF LENS

Patient Lens Care Directions

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

For complete information concerning the care, cleaning, and disinfection of contact lenses, refer to the NOVAKONE (hioxifilcon D) Soft Contact Lenses Patient Information Booklet.

Soaking and Storing Lenses

Instruction for Use:

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

WARNING:

Do not re-use or “top-off” old solution left in lens case since solution re-use 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.

Rub and Rinse Time

Instruction for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting, and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

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

Lens Case Care

Instruction for Use:

Clean contact lens cases with digital rubbing with fresh, sterile disinfecting solutions/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. Air-drying or recapping the lens case lids after use without any additional cleaning methods should be avoided. 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 given by your eye care practitioner or the labeling that came with your case. Contact lens cases can be a source of bacterial growth.

WARNING:

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

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 your lenses have been submersed in water when swimming in pools, lakes, or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

Discard Date on Solution Bottle

Instruction for Use:

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

WARNING:

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

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to **not** use plain water or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution or drops, and to **not** attempt to remove the lens except on the advice of the eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle, and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- First clean the rehydrated lens and then disinfect it using a recommended lens care system.
- If, after soaking, the lens does not become soft or the surface remains dry, **do not use the lens unless it has been examined by your eye care practitioner.**

STORAGE

NOVAKONE Soft Contact Lenses must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, follow the lens care direction in the CARE FOR A DRIED OUT (DEHYDRATED) LENS section in this document.

LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for NOVAKONE Soft Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. Multi-purpose solutions are the preferred choice for use. If using hydrogen peroxide solutions, exposure to peroxide should be limited by using a disc-based system.

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 THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**







REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing NOVAKONE (hioxifilcon D) Soft Contact Lenses or experienced with the lenses should be reported to: Bausch & Lomb Incorporated, 6 Lancaster Pkwy, Lancaster, NY 14086 USA; Telephone: 1-800-253-3669.

HOW SUPPLIED

Each NOVAKONE (hioxifilcon D) Soft Contact Lens is supplied sterile in a glass vial containing 0.9% buffered saline USP. The glass vial is marked with the base curve, power, diameter, manufacturing lot number, and the expiration date of the lens.

SYMBOLS USED ON LABELING

Symbol	Description
	Manufacturer
	Batch code
	Prescription Only (USA)
	Use-by date
	Caution
	Sterilized using steam
CYL	Cylinder power
AX	Cylinder axis
BC	Base curve
ADD	Add power
DIA Ø _r	Diameter
PWR	Power

 Bausch & Lomb Incorporated
6 Lancaster Pkwy
Lancaster, NY 14086 USA
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