

BAUSCH & LOMB Optima™ Toric (hefilcon B) Contact Lenses

IMPORTANT: This package insert is effective as of March 1997 and supersedes all prior inserts for the products described below. 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 patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lenses.

CAUTION: Federal (U.S.A.) Law Prohibits Dispensing Without Prescription

VISION CORRECTION USE

BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lenses.

For: Nearsightedness (Myopia), Farsightedness (Hyperopia), Astigmatism, Not-aphakic

DESCRIPTION

The BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens is a flexible shell with toric surfaces. The lens material, (hefilcon B), is a hydrophilic random copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 45% water by weight when immersed in a sterile saline solution. The BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens is a hemispherical shell of the following dimensions:

• Diameter:	13.0mm to 15.0mm
• Center Thickness:	0.1mm to 1.0mm
• Base Curve:	8.3mm to 9.2mm
• Powers (Spherical):	+6.00D to -9.00D
(Cylinder):	up to 5.00D

The physical/optical properties of the lens are:

Specific Gravity:	1.1
Refractive Index:	1.42
Light Transmittance	C.I.E. Y value - approximately 97%
Water Content:	45%
Oxygen Permeability(Dk):	$13 \times 10^{-11} [\text{cm}^3 \text{O}_2 (\text{STP}) \times \text{cm}] / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) @ 35^\circ \text{C}$
	(Polarographic Method)

ACTIONS

In its hydrated state, the BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS

Daily Wear

The BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens is indicated for vision correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, that exhibit refractive astigmatism up to 5.00 diopters. The lens may be prescribed in spherical powers ranging from +6.00D to -9.00D.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for traditional or frequent/planned replacement wearing schedule, with cleaning, disinfection and scheduled replacement of the lens.

CONTRAINDICATIONS (REASONS NOT TO USE)

DONOTUSE the BAUSCH & LOMB® Optima™ Toric (hefilcon B) 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)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) 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 BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing practitioner of all the risks with contact lens wear. 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 these lenses are worn overnight.
- The need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient
- 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 lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners:

- 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 are 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 should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care practitioner.

- Fluorescein should not be used while the patient is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb residual fluorescein.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should carefully instruct patients about the following 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.
 - 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 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 solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lenses if lens surface does become dried out.
- 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 nonmovement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- 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-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses 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 BAUSCH & LOMB® Optima™ Toric (hefilcon B) 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 gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- 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 and lenses worn on a frequent/planned replacement wearing 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.
- 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 patient should be informed that the following problems may occur:

- Eye stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on 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 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 lenses; 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 lens 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 stinging 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 be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations 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 apply to BAUSCH & LOMB® Optima™ Toric (hefilconB) Contact Lenses. It is very important for the eye care practitioner to give the patient the Patient Information booklet for Optima™ Toric (hefilconB)

Contact Lenses and review it with the patient. For a detailed description of the fitting techniques, refer to the BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lens Professional Fitting and Information Guide, copies of which are available from:

Bausch & Lomb Incorporated
Rochester, New York 14692

Toll Free Telephone Number

In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

Daily Wear:

There may be a tendency for the daily wear patient to over wear 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.

LENS CARE DIRECTIONS

Eye care practitioners 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:

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. 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 the 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.
- Always remove, clean, rinse, enzyme and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**

LENS CARE PRODUCT CHART

The following solutions are recommended by Bausch & Lomb for use with BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lenses; however, eye care practitioners may recommend alternative products and procedures for their patients. All components necessary for lens disinfection, cleaning and storage are available in BAUSCH & LOMB® Care Kits.

Thermal Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Rinsing, Disinfecting & Storing	Commercially available Heat Disinfection Unit for Contact Lenses used with: BAUSCH & LOMB® ReNu® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray BAUSCH & LOMB® SENSITIVE EYES® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Plus Saline Solution
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Thermal Enzymatic Contact Lens Cleaner BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner BAUSCH & LOMB® SENSITIVEEYES® Enzymatic Contact Lens Cleaner

Chemical Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® ReNu® Multi-Purpose Solution BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner

Disinfecting & Storing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution BAUSCH & LOMB® SENSITIVE EYES® Saline Solution BAUSCH & LOMB® ReNu® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray BAUSCH & LOMB® SENSITIVE EYES® Plus Saline Solution
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner BAUSCH & LOMB® SENSITIVEEYES® Enzymatic Contact Lens Cleaner BAUSCH & LOMB® ReNu® 1 Step Enzymatic Contact Lens Cleaner

All Lens Care Systems

Action	Care Product
Rewetting	BAUSCH & LOMB® ReNu® Rewetting Drops BAUSCH & LOMB® SENSITIVE EYES® Drops

- **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.
- **Clean** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the 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 the 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 after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- 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 case is used again, refill it with storage solution. Replace lens case at regular intervals.
- Eye care practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the practitioner.

Heat (Thermal) Lens Disinfection:

- **After cleaning** and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. **To keep the lenses wet during disinfection**, use the solution that is recommended by the lens manufacturer and/or the eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Emergency (Alternate) Method for Heat (Thermal) Disinfection:

- If a heat disinfection unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the 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 it to cool for 30 minutes to complete the disinfection of the lenses.

Note: Use of heat disinfection unit should be resumed as soon as possible.

- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Chemical (Not Heat) Disinfection:

- 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 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.
- 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 on the eyes.
- **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 saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

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 cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

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

CARE FOR A DRIED OUT (DEHYDRATED) OR DRY 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, such as a counter top, apply saline or rinsing solution 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 one hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

CARE FOR A STICKING (NONMOVING) 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.

PRACTITIONER FITTING SETS

All lenses that have been opened must be disinfected after each fitting and at least once each week. Unopened lenses are sterile and need not be disinfected until the vial seal has been broken.

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.**

HOW SUPPLIED

Each Optima™ Toric (hefilcon B) Contact Lens is supplied sterile in a glass vial containing bicarbonate buffered saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, cylinder power, axis, diameter and expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH & LOMB® Optima™ Toric (hefilcon B) Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
Rochester, New York 14692

Toll Free Telephone Number

In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

Bausch & Lomb Incorporated
Rochester, NY 14692

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WARNING: Manufactured with CFC-113, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

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