

en

INSTRUCTIONS FOR USE FOR BAUSCH + LOMB SOFT CONTACT LENSES

Congratulations on joining millions of others around the world who enjoy wearing Bausch + Lomb contact lenses. The information in this instructions for use (IFU) is intended for users of Bausch + Lomb daily disposable soft contact lenses; it includes important product use and safety information. It is essential that users follow these instructions and the directions from your eye care practitioner (ECP) for protection of your vision and eye health. If you have questions on the information contained within this IFU, consult your ECP. These instructions for use apply to the following products:

Table 1: The Contact Lens Products That This IFU Applies To:

PRODUCT/MATERIAL NAME	INDICATION	WATER CONTENT (by weight %)	PACKAGING SOLUTION	REPLACEMENT PERIOD
SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lenses	Spherical	59%	Borate buffered saline with poloxamine	Single-use daily disposable wear, discard lens after each removal
SofLens® daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lenses	Astigmatism			
Bausch + Lomb Naturelle™ daily disposable (hilafilcon B) Cosmetically Tinted Contact Lenses	Spherical			
Biotrue® ONEday (nesofilcon A) Visibility Tinted Contact Lenses	Spherical	78%		
Biotrue® ONEday For Astigmatism (nesofilcon A) Visibility Tinted Contact Lenses	Astigmatism			
Biotrue® ONEday For Presbyopia (nesofilcon A) Visibility Tinted Contact Lenses	Presbyopia			
Bausch + Lomb ULTRA® ONE DAY (kalifilcon A) Visibility Tinted Contact Lenses	Spherical	55%	Phosphate buffered saline with poloxamine	
Bausch + Lomb ULTRA® ONE DAY For Presbyopia (kalifilcon A) Visibility Tinted Contact Lenses	Presbyopia			

HOW THE LENS WORKS (ACTIONS)

The contact lenses in Table 1 transmit between 95% to 99% visible light. When placed on the cornea in their hydrated state, all the contact lenses listed in Table 1 act as a refracting medium to focus light rays on the retina. For the Biotrue® ONEday and Bausch + Lomb ULTRA® ONE DAY contact lens products, the transmittance characteristics are less than 5% in the ultraviolet B (UVB) range of 280nm to 315nm and less than 50% in the ultraviolet A (UVA) range of 316nm to 380nm.

INDICATIONS AND INTENDED USES

Spherical: The Bausch + Lomb daily disposable soft contact lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) and reduction of spherical aberration in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Astigmatism: The Bausch + Lomb daily disposable soft contact lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism), and reduction of spherical aberration in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 5.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Presbyopia: The Bausch + Lomb daily disposable soft contact lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism), presbyopia, and reduction of spherical aberration in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D with add powers ranging from +0.75D to +5.00D.

Refer to Table 1 for information on the replacement period for the contact lens products.

Note: Aphakic means 'lacking a focusing lens inside the eye'.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Bausch + Lomb contact lenses when any of the following conditions exist:

- Allergy, inflammation, infection, irritation, or redness in or around the eye
- Dry eyes (inadequate tear fluid)
- Any eye disease, injury (e.g., corneal abrasion), or abnormality that affects the cornea, conjunctiva, or eyelids
- Reduced corneal sensitivity
- Any systemic disease or poor health (e.g., colds or flu), that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reaction of ocular surfaces or surrounding tissue that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, or viral)
- Patients unwilling or unable to understand or comply with any warnings, precautions, restrictions, or directions
- Use of medications that are contraindicated for contact lens wear
- Any previous medical intervention which may adversely affect the use of the device

WARNINGS

Problems with contact lenses could result in **serious injury** to your eye or in **serious eye infections**, including infectious keratitis. It is essential that you follow your ECP's directions and all labeling instructions for proper use of the lenses. You should be aware of and fully discuss with your ECP the following warnings:

- Strict compliance with your wearing restrictions, wearing schedule, replacement period, and follow-up visit schedule should be followed. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision** (including blindness).
- Daily wear lenses are not indicated for overnight wear and **should not be worn 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.
- Re-use of single-use daily disposable lenses could lead to lens changes that may cause discomfort and poor visual acuity.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your ECP.
- DO NOT use if the package is damaged or unintentionally opened.**
- DO NOT expose contact lenses to non-sterile water (e.g., tap water) while wearing them. **Water can harbor microorganisms that can lead to severe infection and loss of vision (including blindness). If your lenses have been submerged in water when swimming in pools, lakes, or oceans, discard them and replace them with a new pair.**

- The Biotrue® ONEday (nesofilcon A) and Bausch + Lomb ULTRA® ONE DAY (kalifilcon A) UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they **DO NOT** completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

Note: Long-term exposure to ultraviolet (UV) radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

Note: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time.

PRECAUTIONS

You should be aware of and fully discuss with your ECP the following safety precautions:

- Before leaving your ECP's office, be certain that you can remove your lenses promptly or have someone else available to remove them for you.
- Never wear your lenses beyond the period recommended by your ECP.
- 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.
- Be certain that fingers and hands are free of foreign materials before touching your lenses, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle your lenses carefully and avoid dropping them.
- DO NOT touch the lenses with your fingernails.
- Carefully follow the instructions in this leaflet and those recommended by your ECP for handling, insertion, removal, and wearing of contact lenses.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in CARE FOR A STICKING (NON-MOVING) LENS. If non-movement of the lens continues, you should **immediately** consult your ECP.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If your contact lenses come into contact with noxious vapor (e.g., chemical or hazardous substances), or a hazardous environment with ocular impact, they should be removed **immediately**.
- DO NOT freeze the hilafilcon B and nesofilcon A material. The kalifilcon A material is able to withstand lower temperatures without any impact to the product.
- DO NOT share your lenses with others.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

You should be aware that the following problems may occur:

- Eyes 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 (e.g., foreign body, scratched area)
- Excessive watering (tearing) of the eyes or 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, you should IMMEDIATELY REMOVE YOUR 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 your eye. You should discard the lens and insert a new lens. If the problem continues, you should **immediately remove the lens and consult your ECP**.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off your eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

TOPICS TO DISCUSS WITH YOUR EYE CARE PRACTITIONER

As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. You should be instructed as to a recommended follow-up schedule. Patients are advised to consult with their ECP prior to:

- 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.
- Changing the lens type or lens parameter.
- Using any medicine in the eyes. 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 rewetting 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 by the ECP accordingly.
- Wearing contact lenses when in excessively dry or dusty environments.
- Contact your ECP if you have not worn contact lenses for a prolonged length of time.
- Contact your ECP regarding any additional wearing restrictions that apply to you.

WHO SHOULD KNOW THAT YOU ARE WEARING CONTACT LENSES

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you DO NOT wear contact lenses.



PERSONAL CLEANLINESS AND LENS HANDLING

PREPARING THE LENS FOR WEARING

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

HANDLING THE LENSES

- Always insert and remove the same lens first to avoid mix-ups.
- Position the lens on your index finger and examine the lens to be sure that it is moist, clean, clear, and free of any nicks or tears. Make sure the lens is the right way out.



- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly:
 - Less than usual comfort
 - The lens may fold on the eye
 - Excessive lens movement on blink
 - Blurred vision
- If the lens folds and sticks together, place the lens in the palm of your hand and wet thoroughly with the rewetting solution recommended by your ECP. Then GENTLY rub the lens between your index finger and palm in a back and forth motion.
- If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

PLACING THE LENS ON THE EYE

The One Hand Placement Technique (FIG. A and FIG. B)

Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower eyelid. Look down to position the lens properly. Close your eyes for a moment and the lens should center itself on your eye.

The Two Hand Placement Technique (FIG. C and FIG. D)

With the lens on your index finger, use the middle finger of the other hand to pull the upper eyelid against the brow. Use the middle finger of your placement hand to pull down the lower eyelid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.



FIG. A

FIG. B

FIG. C

FIG. D

If the lens feels uncomfortable, then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO).

CENTERING THE LENS

If after placement of the lens your vision is blurred, check for the following:

- The lens is not centered on the eye. To center a lens, follow one of the procedures below:
 - Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and slide the lens towards the center of the eye.
 - OR**
 - Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.
- If the lens is centered, remove the lens and check for the following:
 - Cosmetics or oils on the lens. Discard the lens and use another lens.
 - The lens is on the wrong eye.
 - The lens is inside-out (it would not be as comfortable as normal).

If you find that your vision is still blurred after checking the above, remove both lenses and consult your ECP.

REMOVING THE LENS

- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.
- Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower eyelid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.
- Remove the other lens by following the same procedure.
- Use rewetting drops recommended by your ECP if lens is difficult to remove.

Note: If this method of removing your lens is difficult for you, your ECP will provide you with an alternative method.

CARE FOR A STICKING (NON-MOVING) LENS

If a lens sticks (stops moving), put a few drops of the rewetting solution recommended by your ECP into your eye. DO NOT use plain water or anything other than the recommended solutions. DO NOT attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution, immediately contact your ECP. DO NOT attempt to remove the lens except on the advice of your ECP.



INFORMATION SPECIFIC TO MONOVISION OR MULTIFOCAL WEARER

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision or multifocal contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.
- Some patients had trouble adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches, and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.
- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision or multifocal correction if you pass your driver's license requirements with monovision or multifocal correction.
- Some patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your ECP having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some patients require supplemental spectacles to wear over the monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this option with your ECP.
- It is important that you follow your ECP's suggestions for adaptation to monovision or multifocal contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fitted with a monovision or multifocal correction is most appropriately left to the ECP in conjunction with you, after carefully considering and discussing your needs.**

EMERGENCIES

If chemicals or hazardous substances of any kind (e.g., household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR ECP OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF SERIOUS INCIDENTS

Any side effects, adverse reactions, or product complaints from use of Bausch + Lomb contact lenses should be reported to the manufacturer. Country specific information can be found on www.bausch.com/contactus. Reporting of serious incidents from use of Bausch + Lomb contact lenses should be reported to the manufacturer and the relevant competent authority.

HOW BAUSCH + LOMB SOFT CONTACT LENSES ARE SUPPLIED

Each lens is provided in a foil sealed plastic container containing packaging solution. The contact lenses are supplied steam sterilised.

STORAGE CONDITIONS

Reference the temperature symbol below for the temperature storage conditions, if applicable.

 The products below must not be stored below 1°C (34°F):

SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lenses
SofLens® daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lenses
Bausch + Lomb Naturelle™ daily disposable (hilafilcon B) Cosmetically Tinted Contact Lenses
Biotrue® ONEday (nesofilcon A) Visibility Tinted Contact Lenses
Biotrue® ONEday For Astigmatism (nesofilcon A) Visibility Tinted Contact Lenses
Biotrue® ONEday For Presbyopia (nesofilcon A) Visibility Tinted Contact Lenses



Bausch + Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA











Bausch + Lomb Incorporated
Cork Road Industrial Estate
Waterford, X91 V383, Ireland

EU IMPORTER

Bausch + Lomb Netherlands B.V.
Koolhovenlaan 110, 1119 NH Schiphol-Rijk
P.O. Box 75774, 1118 ZX Schiphol
The Netherlands

SYMBOLS & ABBREVIATIONS GLOSSARY

The following may appear on the label or the carton of your product:

	Medical device
	Fee paid for waste management
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Sterilized using steam
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Consult instructions for use (Explanation of symbols is also available at www.bausch.com/symbols)
	Caution
DIA Ø _r	Diameter
BC	Base curve
PWR F _v	Power
AX	Cylinder axis
SPH	Sphere power
CYL	Cylinder power
ADD	Add power

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