

Bausch & Lomb
SofLens®
daily disposable
(hilafilcon B)

with Aspheric Optics

Visibility Tinted Contact Lenses
For Daily Wear

PATIENT INFORMATION BOOKLET



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Introduction

The instructions in this booklet apply to the Bausch & Lomb SoftLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lenses. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care professional for the patient booklet or instructions that apply to your brand or type of contact lenses. For Bausch & Lomb SoftLens daily disposable (hilafilcon B) Visibility Tinted Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care professional answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear, you should discuss with your eye care professional the effects of contact lenses on your eyes and the risks associated with wearing contact lenses. You also should read the sections of this booklet entitled “Warnings”, “Adverse Reactions”, “Precautions”, and “Wearing Restrictions and Indications”. Ask your eye care professional to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care professional. Your Bausch & Lomb SoftLens daily disposable (hilafilcon B) Visibility Tinted

Contact Lenses have been prescribed for single-use disposable wear, and should be discarded each time lenses are removed from your eyes.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in this booklet entitled “Personal Cleanliness and Lens Handling”, as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care professional. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule, and regular check-up visits to your eye care professional are also necessary for the proper and safe use of contact lenses.

It is important not to wear your lenses longer than recommended by your eye care professional since doing so increases the risk of adverse effects.

Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not overwear your lenses simply because they remain

comfortable and you are not experiencing a problem. Only your eye care professional, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of this booklet entitled “Warnings” and

“Adverse Reactions”. (Refer to “Glossary of Medical Terms” for description of medical terms used in this booklet). Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

Wearing Restrictions and Indications

The Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00

diopeters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens has been prescribed for single-use disposable wear, and is to be discarded after each removal.

Contraindications (Reasons Not To Use)

DO NOT USE the Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted 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
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

Warnings

You should be aware of and fully discuss with your eye care professional the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in **serious injury** to your eye. It is essential that you follow your eye care professional's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are not indicated for overnight wear, and **you should not wear lenses while sleeping**. Clinical studies have shown that the risk

of serious adverse reactions is increased when daily wear lenses are worn overnight.

- Strict compliance with your wearing restriction wearing schedule, and follow-up visit schedule should be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly consult your eye care professional.

Precautions

You should be aware of and fully discuss with your eye care professional the following safety precautions:

Handling Precautions:

- 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.
- Before leaving your eye care professional's office be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of 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 lens with your fingernails.
- Carefully follow the handling, insertion, removal,

cleaning disinfecting, storing and wearing instructions in this booklet and those prescribed by your eye care professional.

- 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.

Lens Wearing Precautions:

- Never wear your lenses beyond the period recommended by your eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Nonmoving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Topics to Discuss with Eye Care Professional

- 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 should be advised 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.
- Always contact your eye care professional before using any medicine in the eyes.

Who should know that you are wearing contact lenses:

- Inform your doctor (health care professional) 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 not wear lenses.

Ask your eye care professional whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

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 (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 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 on the eye. If the problem continues, you should **immediately remove the lenses and consult your eye care professional.**

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.**

Personal Cleanliness and Lens Handling

1. PREPARING THE LENS FOR WEARING:

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- 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.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. HANDLING THE LENSES:

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Position the lens on your index finger and examine it to be sure that it is moist, clean, and free of any nicks or tears.
- 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.
 - a. Less than usual comfort
 - b. The lens may fold on the eye
 - c. Excessive lens movement on blink
 - d. Blurred vision
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rewetting solution. (Refer to the Lens Rewetting Products Chart for the solutions available from Bausch & Lomb). Then GENTLY rub the lens between your index finger and palm in a gentle 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.

3. PLACING THE LENS ON THE EYE

There are other methods of lens placement. If the following methods are difficult for you, your eye care professional will provide you with an alternate method.

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

- The lens is not centered on the eye (see “Centering the Lens,” next in this booklet).
- If the lens is centered, remove the lens (see “Removing the Lens” section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens is inside-out (it would also not be as comfortable as normal).

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

The One Hand Placement Technique

Place the lens on your index finger. 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 lid. Look down to position the lens properly. Close your eyes for a moment; the lens will center itself on your eye.



The Two Hand Placement Technique

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

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 the section of this booklet entitled “Adverse Reactions.”



4. CENTERING THE LENS

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. 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 gently 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.

5. REMOVING THE LENS

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. 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 lid 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.

6. CARE FOR A STICKING (NONMOVING) LENS

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care professional into your eye. In this case, 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 or drops, contact your eye care professional immediately. Do not attempt to remove the lens except on the advice of your eye care professional.

7. EMERGENCIES

If chemicals of any kind (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 eye care professional OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

LENS REWETTING PRODUCTS AVAILABLE FROM BAUSCH & LOMB:

Bausch & Lomb ReNu® Lubricating and Rewetting Drops
Bausch & Lomb Sensitive Eyes® Drops

Instructions for the Monovision Wearer

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.
- Some patients have experienced difficulty 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, which 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 correction if you pass your state drivers license requirements with monovision correction.
- Some monovision 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 eye care professional 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 monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this option with your eye care professional.
- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

Personal Wearing Record Schedule

Your eye care professional will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record.

| DAY | DATE | HOURS TO BE WORN | HOURS WORN |
|-----|------|------------------|------------|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 10 | | | |

| DAY | DATE | HOURS TO BE WORN | HOURS WORN |
|------------|-------------|-------------------------|-------------------|
| 11 | | | |
| 12 | | | |
| 13 | | | |
| 14 | | | |
| 15 | | | |
| 16 | | | |
| 17 | | | |
| 18 | | | |
| 19 | | | |
| 20 | | | |
| 21 | | | |
| 22 | | | |

Check-Up Visits

Regular check-up examinations by your eye care professional are an important part of wearing contact lenses. It is recommended that you follow your eye care professional's directions for follow up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care professional to refer you to a contact lens professional in your new location. Use the space below to record your appointments.

VISIT SCHEDULE

| | | |
|-----|-------|-------|
| 1. | _____ | _____ |
| | Date | Time |
| 2. | _____ | _____ |
| | Date | Time |
| 3. | _____ | _____ |
| | Date | Time |
| 4. | _____ | _____ |
| | Date | Time |
| 5. | _____ | _____ |
| | Date | Time |
| 6. | _____ | _____ |
| | Date | Time |
| 7. | _____ | _____ |
| | Date | Time |
| 8. | _____ | _____ |
| | Date | Time |
| 9. | _____ | _____ |
| | Date | Time |
| 10. | _____ | _____ |
| | Date | Time |

Eye Care Professional Information

PLEASE FILL OUT FOR READY USE

Name: _____

Address: _____

Phone: _____

Other Information: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

Bausch & Lomb Incorporated
Rochester, New York 14609


Glossary of Medical Terms

| | |
|----------------------------------|---|
| Ametropia | Abnormal vision requiring correction for proper focus |
| Myopia | Nearsighted |
| Hyperopia | Farsighted |
| Aphakic | Lacking a crystalline lens (focusing lens inside the eye) |
| Non-aphakic | Not lacking a crystalline lens |
| Acute inflammation | Sudden swelling, redness and pain |
| Subacute inflammation | Gradual swelling, redness and pain |
| Anterior chamber | Internal portion of the eye, between the cornea and iris |
| Cornea | Clear, front covering of the eye |
| Conjunctiva | Membrane that lines the eyelids and the white part of the eye |
| Corneal ulcer | A sore or lesion on the cornea, which left untreated could lead to permanent loss of vision |
| Microbial keratitis | An infected corneal ulcer |
| Hypoxia | Lack of oxygen |
| Epithelial | Layer of cells on the surface of the cornea |
| Epithelial microcysts | A small abnormal structure (cyst) in the front surface of the eye |
| Endothelial polymegathism | Irregular cell size and shape |
| Neovascularization | Small blood vessels growing into the cornea |
| Iritis | Internal inflammation of the colored part of the eye (iris) |

Symbol Reference Guide

For labels and cartons:

0050 Quality System Certification Symbol

 Fee Paid for Waste Management


 Sterile Using Steam or Dry Heat

 See Instruction Leaflet


DIA \varnothing_r Diameter

 Single Use Only

EXP  Use by Date (Expiration Date)

 Batch Code

 Authorised Representative in European Community

 Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.

PWR (F_V) Diopter (Lens Power)

BC Base Curve

