

PATIENT INFORMATION BOOKLET

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses

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

INTRODUCTION:

The instructions in this booklet apply to the BAUSCH & LOMB® PureVision™ (balafilcon A) 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 PureVision 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 or continuous 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, which are greater with continuous wear contact lens use. 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.

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 the sections of 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 replacement 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 to not 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 wear your lenses for longer periods than your prescribed wearing schedule 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® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 30 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-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 for Frequent/Planned Replacement or Disposable Wear in spherical powers ranging from +8.00D to -20.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned Replacement Wear, the PureVision Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR

When prescribed for Disposable Wear, the PureVision Contact Lens is to be discarded after each removal.

WEARING RESTRICTIONS

The PureVision Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care professional. **For extended wear, once the lenses are removed, your eyes should have a rest without lens wear for at least one overnight, as recommended by your eye care professional.** Your eye care professional will tell you how long to rest your eyes in between wearing periods and will also recommend a replacement period and appropriate lens care products.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the BAUSCH & LOMB® PureVision™ (balafilcon A) 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 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® PureVision™ (balafilcon A) Visibility Tinted Contact Lens
- 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 and lens care products 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 and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Strict compliance with your lens care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of continuous wear contact lenses than among users of daily wear contact lenses. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, continuous wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or restriction of continuous wear. The epithelial conditions are reversible upon discontinuation of continuous wear.

The long term risk of microbial keratitis has not been determined for this lens. Post-marketing studies are in progress.

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The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners views of continuous wearing times vary from not prescribing continuous wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing continuous wearing periods from 1 to 30 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your eye care professional.

PRECAUTIONS:

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

Specific Precautions:

- Always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.

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.

Solution Precautions:

- **Do not use the Allergan® Ultracare® Disinfecting System or any of its components (Ultracare® Disinfecting Solution, Ultracare® Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme® Enzymatic Cleaner) to clean and disinfect the PureVision Contact Lens.**
- 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.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting 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.
- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not use chemical disinfection solutions with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.

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.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

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Topics to Discuss with the 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 the Patient is 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 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)

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- 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. Place the lens in the storage case and contact your eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, 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.

CLINICAL STUDY:

A 12-month clinical study of the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses showed the lens is safe and effective for vision correction for up to 30 days of continuous wear.

A total of 820 subjects were enrolled in the clinical study. Six hundred ten (610) subjects completed the one-year study. Subjects were fitted with a PureVision Contact Lens on one eye and a Control lens the other eye. Subjects were instructed to replace the PureVision Contact Lens with a new lens every 30 days, and to wear the Control lens overnight for up to six consecutive nights per week. Eyes had one night without lens wear after the scheduled removal. The Control lens was to be replaced with a new lens every 14 days.

Study Results:

All predetermined safety and efficacy study endpoints were successfully achieved. The study showed the PureVision Contact Lenses, when worn on a 30-day continuous wear basis, is equivalent in safety and efficacy to the Control lens when worn on a 7-day continuous wear basis.

Safety:

There were no reports of permanent loss of vision for either the PureVision Contact Lenses or the Control lenses. Of the subjects that entered into the continuous wear phase of the study, 2.9% developed corneal infiltrates of the severity identified in the study protocol as a study safety endpoint in the PureVision eye, compared to 1.3% in the control eyes. It should be noted that the PureVision Contact Lens and Control lenses were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

Other reported adverse events included corneal scars, keratitis, conjunctivitis, ocular infections, and inflammatory reactions. Subjects reported other less serious problems such as dryness, discomfort,

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and burning and stinging. These symptoms were reported at equivalent rates for the PureVision Contact Lens and the Control lens.

Effectiveness:

Not all of the subjects were able to wear their lens for the maximum 30-day period. In this U.S. clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. Some subjects were discontinued from the study because they were not able to wear the PureVision Contact Lens for 30 days. For the subjects that completed the study, the average continuous wear time for the PureVision Contact Lens was 28.0 days per month. The same subjects reported they were able to wear the PureVision Contact Lens at least 22 days continuously 94% of the times they were asked.

The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study. For the 610 subjects that completed the study, visual acuity of 20/20 or better was reported for 87% of the measurements for the PureVision Contact Lens. Similarly, visual acuity of 20/25 or better was reported 98% of the time.

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 mixups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, 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 rinsing or storing solution. (Refer to the Lens Care 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 this gentle rubbing does not work, soak the lens in the recommended solution in your lens case until the lens has resumed its normal shape. 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.
 - Keep the lens wet in the solution recommended by your eye care professional.
 - Never place a lens on the eye unless it has been fully hydrated (wet) with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from BAUSCH & LOMB.)

3. **Placing the Lens on the Eye:**

(Application instructions in step-by-step format with graphics will be included in Final version)

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. 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

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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.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

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Note: If this method of removing your lens is difficult for you, your eye care professional will provide you with an alternate method.

LENS WEARING SCHEDULES:

Your eye care professional may either recommend using the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens as a disposable lens or a frequent/planned replacement lens.

Regardless of the schedule prescribed for you, once a lens is removed at the end of the prescribed wearing period, your eye should have a rest period with no lens wear of overnight or longer, as recommended by your eye care professional.

Disposable Lens Wear:

No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Frequent/Planned Replacement:

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

CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING):

1. Basic Instructions:

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** [and neutralize (for hydrogen peroxide systems)] your lenses after each removal, using the lens care regimen recommended by your eye care professional. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

You should adhere to the lens care regimen recommended by your eye care professional. Failure to follow the lens care regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended lens care regimen, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care professional's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care professional should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of these Patient Instructions for the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended chemical (not heat) lens care system 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.**
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period prescribed by your eye care professional.
- Never rinse your lenses in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. 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 your eye care professional. Follow the instructions provided in the disinfection solution labeling.
- 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 your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with **fresh** storage solution. Replace lens case at regular intervals.
- Your eye care professional may recommend a lubricating/rewetting solution for your use. **Lubricating/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

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2. Chemical (Not Heat) Disinfection:

- Clean the contact lenses with the cleaning solution recommended by your eye care professional and thoroughly rinse them with the recommended rinsing solution.
- **After cleaning**, and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by your eye care professional.
- 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 closed storage case until ready to put on your eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to your eyes. A thorough rinse in fresh sterile saline solution prior to placement on your eye should reduce the potential for irritation.

3. Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme cleaning may be recommended by your eye care professional. 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 your 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, you should carefully follow the instructions in the enzymatic cleaning labeling.

4. 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 each time you remove the contact lenses from it. Lens cases should be replaced at regular intervals.

5. 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. 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.

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6. 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 the recommended 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 1 hour until it returns to a soft state.
- Clean lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, **DO NOT USE THE LENS UNTIL IT HAS BEEN EXAMINED BY 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 CARE PRODUCTS CHART

The following solutions are available from Bausch & Lomb for use with all Bausch & Lomb Contact Lenses; however, eye care professionals may recommend alternative products and procedures which should be followed by the patient. BAUSCH & LOMB® Care Kits are available for lens disinfection, cleaning, and storage.

Chemical Lens Care System

<u>Action</u>	<u>Care Product</u>
Cleaning	BAUSCH & LOMB® ReNu MultiPlus® Multi-Purpose Solution
	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB® ReNu MultiPlus® Multi-Purpose Solution
	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu MultiPlus® Multi-Purpose Solution

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	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® 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® SENSITIVE EYES® Enzymatic Cleaner
	BAUSCH & LOMB® ReNu® 1 Step Enzymatic Cleaner
	BAUSCH & LOMB® ReNu® 1 Step™ Daily Protein Remover Liquid

All Lens Care Systems

Action

Rewetting

Care Product

BAUSCH & LOMB® ReNu MultiPlus® Lubricating and Rewetting Drops

BAUSCH & LOMB® ReNu® Rewetting Drops

BAUSCH & LOMB® SENSITIVE EYES® DROPS

BAUSCH & LOMB® ReNu® Preservative Free Lubricating & Rewetting Drops

- Note: Some solutions may perform more than one function in the care regimen, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Draft Patient Information Booklet

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.**

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PERSONAL WEARING SCHEDULE RECORD

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			
11			
12			
13			
14			

Draft Patient Information Booklet

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 practitioner 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

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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 you, **DO NOT WAIT** for your next appointment. **TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.**

NAME AND ADDRESS OF MANUFACTURER:

Bausch & Lomb Incorporated
 Rochester, New York 14603

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 a permanent loss of vision
Ulcerative 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)

Store lenses at room temperature (60°F - 80°F, 15°C - 25°C)

Patent Number: BAUSCH & LOMB INCORPORATED
 [patent information placed here] Rochester, NY 14603

[part number] [month/year of issue] Printed in U.S.A.

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BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses Soft Contact Lenses for Continuous Wear

IMPORTANT:

The following basic information about contact lens wear and BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses is provided for you by BAUSCH & LOMB.

If you are interested in PureVision lenses, please see a licensed eye care professional. Based on your individual needs, your eye care professional will determine if PureVision lenses are right for you and how many days and nights you can wear them.

What are PureVision Contact Lenses?

PureVision lenses are soft contact lenses made of balafilcon A, a silicone hydrogel material that contains 36% water. This lens material provides a high level of oxygen to your eyes and has been surface treated to wet with your tears.

How are PureVision Contact Lenses used?

The lenses are worn on the cornea (front part of the eye) and used to correct vision by refocusing light rays onto the retina (back part of the eye).

The lenses may be used to correct nearsightedness (myopia) or farsightedness (hyperopia). They may be prescribed for:

- ◆ Daily wear use – worn only while you are awake
- ◆ Continuous wear use – worn while you are awake and asleep
 - They may be worn for up to 30 nights (one month) of continuous wear based on how your eyes respond to lens wear and your eye care professional's recommendation.

Can everyone wear PureVision Contact Lenses for 30 nights of continuous wear?

Not everyone can reach the maximum wear time of 30 continuous nights. During a U.S. clinical study, 610 of the 820 subjects entered into the study completed one-year of lens wear. Subjects were required to maintain a minimum wearing time in order to continue in the study. Some subjects were not able to achieve the minimum wearing time and were discontinued from the study for that reason. At each follow-up visit subjects were asked how long they wore their lenses. The subjects that completed the study reported wearing the lens between 22 to 30 days 94% of the times they were asked.

Your eye care professional may recommend a shorter wearing time depending on your individual needs, and you should always adhere to his or her recommendations. Once lenses are removed, your eyes should have a rest without lens wear for at least one overnight.

I already wear PureVision lenses. Can I now increase my wearing time to 30 days?

No. You must consult with your eye care professional first. Based on your specific needs, your eye care professional will recommend a wearing schedule for you.

Who should not wear contact lenses?

You should not wear contacts if you:

- ◆ Have an eye infection or inflammation (redness & swelling).
- ◆ Have an eye disease, eye injury or dryness that interferes with contact lens wear.
- ◆ Have a systemic disease that may be affected by or impact lens wear.
- ◆ Have certain types of allergic conditions.
- ◆ Are using certain medications, such as some eye medications.

What are the risks of wearing contact lenses for continuous wear?

While there are many benefits of wearing contacts, sometimes problems can occur and the risk of serious problems is greater when lenses are worn overnight. You should carefully discuss the benefits and risks of continuous wear lenses with your eye care professional.

Historically, overnight lens wear has been associated with an increased risk of developing a serious ocular infection, such as a corneal ulcer. A corneal ulcer may develop rapidly and cause eye pain, redness or blurry vision as it progresses. If left untreated, a scar, and in rare cases loss of vision, may result.

In addition, studies have shown that smoking increases the risk of corneal ulcers for those who wear lenses overnight.

What are other possible side effects of overnight lens wear?

An inflammation of the cornea called infiltrative keratitis is another potential side effect. In the U.S. clinical study patients were fit with the PureVision lens in one eye and a Control lens in the other eye. During the one-year study 2.9% of the 820 eyes that were fit with the PureVision lens in one eye experienced infiltrative keratitis. Rates are expected to be higher when lenses are fit in both eyes. Other less serious side effects were mild forms of dryness, discomfort, and burning and stinging.

Are there times when you should not wear contact lenses?

Your eye care professional can tell you about situations or environmental conditions that may be inappropriate for contact lens wear. Some examples are:

- ◆ Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- ◆ Fumes, smoke or vapors should be avoided to reduce the chance of lens contamination.

How often do I replace the lenses and how do I care for them?

Lenses should be replaced every month, or as recommended by the eye care professional. When removed from your eyes in between replacement times, they should be cleaned and disinfected with a chemical disinfection system (not heat), if not replaced with a new lens.

What are some important things to remember?

- ◆ While wearing contacts your eyes should look well, feel comfortable and vision should be clear.
 - If you have a problem, immediately remove your lenses and contact your eye care professional.
- ◆ Carefully follow your eye care professional's instructions for lens wear, care and replacement.
 - Never wear your lenses for longer periods than prescribed for you.
- ◆ See your eye care professional for follow-up care and periodic checkups.

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses Soft Contact Lenses for Continuous Wear

What if I have other questions about PureVision Contact Lenses?

It is essential to see and talk with your eye care professional about your eye health and to obtain complete information about PureVision contact lenses. If you have questions, discuss them with your eye care professional.

If you want to read more about PureVision Contact Lenses, ask your eye care professional for the patient instruction booklet available from BAUSCH & LOMB or the package insert written for the eye care professional.

For more information call 1-800-553-5340 or visit our website at www.Bausch.com.

Bausch & Lomb Incorporated

Rochester, NY 14603

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U.S. Patents 5610252, 4997897 and other patents.

Printed in U.S.A.

11/01