DESCRIPTION
The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is a soft hydrophilic contact lens that is short surfactan sphere consisting of multiple amphiphilic zones with a spherical base curve. The most steep power in the center of the lens, progressing to more minus in the peripheral. The lens material, balafilcon A, is composed of silicone-carbonate, non-ionic-pyroclastics, a silicon crosslinker and a vinyl alanine wetting monomer, and a 36% water by weight in a sterile borate buffered saline solution. This lens is tinted blue with up to 300 ppm of Reactive Blue dye 24.

The physical/ optical properties of the lens are:
Specific Gravity: 1.064
Refractive Index: 1.426
Light Transmittance: C.I. value, at least 95%
Water Content: 36%
Oxygen Permeability: 91.9 × 10⁻¹⁰cm³ (STP) / cm² (s cm Hg) × 35% Polychromatic Method (Boundary and Edge Corrected)
Use by Date: 10 + 10⁻¹⁰cm³ (STP) / cm² (s cm Hg) × 35% Polychromatic Method (Boundary Corrected/Non-Edge Corrected)

The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses, with AirGard® technology lens material, are manufactured by a cast molding process and are treated with the Performa® surface treatment process which transforms hydrophilic silicone to hydrophilic aUO. The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses may be prescribed for Frequent/ Planned Replacement or Disposables Wear.

PRECAUTIONS
Due to the small number of patients enrolled in clinical investigations of all, no patient selection, design configurations, or lens parameters available in the package material, but are evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for portions of the power range, plus some low minus power lenses. In the U.S. clinical study of the Pure Vision (spherical) lens, the rate of infiltrates was found to be higher with both higher powers of lenses and those lenses that were primarily used for multiple daily wear (see Clinical Studies section of the package insert).

The potential impact of these factors on the patient’s ocular health must be carefully weighed against the patient’s need for refractive correction. Therefore, the prescribing eye care professional should carefully monitor the contact lens ocular health of the patient and lens performance on eye.

Patients who wear corneal contact lenses, such as the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens, to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

This package insert and fitting guide is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with the information and the instructions for proper use of lenses and lens care products, including the lens case.

HOW THE LENS WORKS (ACTIONS)
In the hydrated state, the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS
The Bausch + Lomb PureVision®2 For Presbyopia (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 lenses are intended for the correction of refractive astigmatism (myopia, hyperopia, and astigmatism) and presbyopia in aphakic, and/or pseudophakic patients with non-diseased eyes, exhibiting astigmatism of up to 2.00 diopters, that does not interfere with visual acuity. The lenses may be prescribed for Frequent/ Planned Replacement Wear orDisposable Wear in spherical powers ranging from +0.00 to -8.00 and +0.50 to -5.00 when prescribed for up to 30 days of extended wear and from +0.25 to -4.00 for daily wear or extended wear up to 7 days with add powers ranging from +0.75 to +5.00.

Note: See the WARNINGS relative to the relationship between lens wearing schedule and corneal complications.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/ Planned Replacement Wear, the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses to be disinfected and rinsed each time it is removed from the patients eyes 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 Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses to be discarded after each removal.

CONTRAINDICATIONS
DO NOT USE the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses 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 insufficient of visual acuity (diminished vision)
• Corneal hypoxia (reduced corneal sensitivity)
• Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses

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IMPORTANT
This package insert and fitting guide has been developed to provide professionals with information regarding characteristics of the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses and to illustrate fitting procedures. It is effective as of March 2017 (2017:03:31) and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with the information and the instructions for proper use of lenses and lens care products, including the lens case.

Requests for Eye Care Professionals
Due to the small number of patients enrolled in clinical investigations of lenses, all refractive power, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for portions of the power range, plus some low minus power lenses. In the U.S. clinical study of the Pure Vision (spherical) lens, the rate of infiltrates was found to be higher with both higher powers of lenses and those lenses that were primarily used for multiple daily wear (see Clinical Studies section of the package insert).

The potential impact of these factors on the patient’s ocular health must be carefully weighed against the patient’s need for refractive correction. Therefore, the prescribing eye care professional should carefully monitor the contact lens ocular health of the patient and lens performance on eye.

Patients who wear corneal contact lenses, such as the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens, to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.


Reference Guide

10 YEARS OF ADVANCEMENT
Since its introduction in 2007, the Bausch + Lomb PureVision®2 Contact Lens has revolutionized the practice of contact lens technology, offering significant improvements over its predecessor, the PureVision® Contact Lens. These advancements have allowed patients to enjoy better vision, comfort, and a more natural feel.

- **Improved vision correction**: The PureVision®2 offers superior optical performance, providing patients with clearer vision, especially in low light conditions.
- **Comfort enhancement**: The lens’ design allows for increased oxygen permeability, reducing dry-eye symptoms and increasing overall comfort.
- **Easier lens care**: The materials used in the PureVision®2 make lens cleaning and disinfecting easier and more efficient, reducing the risk of bacterial contamination.
- **Durability and reliability**: The PureVision®2 has demonstrated exceptional durability, with studies showing it outperforms other lenses in terms of wear time and comfort.

These advancements, coupled with the PureVision®2’s adaptability to various eye conditions, have made it a preferred choice for both patients and eye care professionals.

In conclusion, the Bausch + Lomb PureVision®2 Contact Lens has been a significant milestone in contact lens technology, setting new standards for comfort, vision, and convenience. Its success continues to propel the field forward, driving further innovation in the contact lens industry.
The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Light Transmittance: C.I.E. value—at least 95%

The physical / optical properties of the lens are:
- The power is in the center of the lens, progressing to more minus in the periphery. The lens wear after the scheduled removal. The Control lens was to be replaced with a continuous wear basis. A total of 1640 eyes (820 subjects) were enrolled into this 12-month study, compared to a conventional Control lens worn on a 7-day following: a weakening of the cornea’s resistance to infections, particularly during a keratitis infection.

- Infectious corneal ulceration is one of the most serious potential adverse reactions. Complete the lens for a Dry-Out (Dehydrated) Lens in the Patient Information Booklet if lens surface does become dried out.

- Do not substitute or alter lens care systems or solutions unless indicated in the lens care system labeling directions.

- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling directions.

- Do not heat the chemical division solution or lenses.

- The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal. The PureVision® contact lens when placed on the cornea, acts as a refracting medium to correct the power used.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of keratitis infection.

- Reduced sharpness of vision (poor visual acuity)

- The objective of this 12-month study was to evaluate the safety and efficacy of the PureVision® contact lens and Control lenses were calculated. The difference in rates between the two lens types was determined and a 95% confidence interval for the difference was calculated. For each key endpoint a “clinically significant difference” in the rates was established before the study started. These “clinically significant differences” were as follows:

- Lens Wearing Precautions
  - Never wear lenses beyond the period recommended by the eye care professional.
  - If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If loosening of the lens continues, the patient should be instructed to immediately consult his or her eye care professional.
  - Avoid, flexibly, all harmful or irritating vapors and fumes while wearing lenses.
  - If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Lens Care Precautions
  - Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury always rinse and store the lens cases新鲜 with fresh, sterile rinsing solution and allow to dry.
  - Lenses can be replaced monthly or as frequently as recommended by the lens manufacturer or eye care professional.
  - Contact lenses should be replaced with a new or cleaned lens case.
  - Always avoid fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lens absorbs this dye and becomes discolored. Whenever fluorescein is used on the eye, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.

- Solution Precautions
  - Do not use the Allergan Ultraclean Disinfecting System or any of its components (Ultraclean Solution, Ultraclean Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme Enzymatic Cleaner) to clean and disinfect the Bausch + Lomb PureVision®2 for balafilcon A Visibility Tinted Contact Lens.

- The patient must be trained to always discard disposable lenses and lens wash on a frequent / Planned Replacement schedule after the recommended wearing schedule has been completed.

- Some patients will not be able to tolerate continuous wear even if they can tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear without a lens will be included.

- Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eye care professionals should conduct early and frequent follow-up examination to determine the outcome to continuous wear.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eye or patient. The patient should be instructed to as recommended a follow-up schedule.

- Aphakic patients should not be fitted with a Bausch + Lomb PureVision®2 for balafilcon A Visibility Tinted Contact Lens until the determination is made that the eye has healed completely.

- Eye care professionals should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb PureVision®2 for balafilcon A Visibility Tinted Contact Lens Insert Card which contains information from Bausch + Lomb and understands its content prior to dispensing the lenses.

- Handling Precautions
  - Always wash and rinse hands before handling lenses. Do not use cosmetics, lotions, soaps, creams, disinfectants, or sprays in or on the eyes. 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 sure that the fingers or hands are free of foreign materials before touching lenses, as microscopical traces of the lenses may occur, causing distorted vision and injury to the eye.

- Always handle lenses carefully and avoid dropping them.

- Do not touch the lenses with fingernails.
It should be noted that the PureVision® contact lens and Control lenses were each fit for only the right or left eye for each subject. Rates per subject are expected to be higher than rates per eye for both eyes.

Efficacy Outcomes

The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study for the 680 subjects. The daily study visual acuity of 20/20 or better was reported by 87% and 88% of the measurements for the PureVision contact lens and Controls, respectively. Similarly, visual acuity of 20/20 or better was reported 98% and 97% of the time for the PureVision contact lens and Control lenses.

Wearing Conditions

In the U.S. clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. For the subjects that completed the study, the average continuous wear time for the PureVision lenses was at least 20 days per month. From the 2-Month visit through the 12-Month visit, all visits these same subjects reported they were to wear the PureVision contact lenses at least 22 days continuously 94% of the time they were asked.

During the course of the study, 15 subjects were discontinued from the study because they were not able to wear the PureVision lenses for 21 days or less. Twenty-two (22) subjects were discontinued from the study because they were not able to wear the Control lenses for 21 days or less.

Overnight Corneal Swelling

Two separate studies with the PureVision® Lenses (spherical) assessed the corneal swelling responses following overnight wear for 30 days. In the first study, 30 subjects each wore either a +1.00D, +3.00D, or +6.00D PureVision contact lens and an equivalent power level of a conventional hydrogel (Control) lens on the same eye for one week. Each eye was studied at the midpoint of the patient’s habitual reading distance. The corneal swelling was significantly greater and more pronounced in the Control lenses (19%) than in the corneal swelling response measured under similar conditions. In the second study, the corneal swelling response was measured under similar conditions. In this study, the response to a -3.00D PureVision contact lens (20%) was compared to the swelling response to no lenses wear (9%) The response to the lenses was not statistically significant.

POST-APPROVAL EXTENDED WEAR STUDY

The purpose of this post-approval study was to investigate the occurrence of serious adverse events that are unusual or unexpected in normal, daily, all-day-wear contact lens wear. Serious adverse events were any of microbial keratitis (including corneal ulcer) or a loss of more than two lines of best corrected visual acuity.

During the post-approval study, there were no cases of microbial keratitis and no serious adverse events reported as noted in normal, daily, all-day-wear contact lens wear. However, there were some cases of surface damage reported as noted in normal, daily, all-day-wear contact lens wear.

Purcell performed a lens replacement study in which a patient functions.

The patient to only drive during optimal driving conditions. After adaptation and success several weeks of wear (when adaptation is occurring), it may be advisable for the adaptation process. This is particularly true when driving at night. Before driving a lens should be stressed to these patients. The wearing schedule should be determined by each individual patient, based upon a full examination and patient history as well as the advantages of clear near vision in straight ahead and upward gaze that may reduce visual acuity and depth perception for distance and near tasks. During glasses. Each patient should understand that monovision can create a vision compromise.

Other Lens-Related Adverse Events

In addition to the outcomes described above, the following lens related adverse events were noted. The adverse events included conjunctival disorders or strabismus or other ocular disorders (e.g., giant papillary conjunctivitis). Other Important Lens-Related Adverse Events

The Study Strengths and Study Limitations should be considered when evaluating the results of the study. The study was not controlled with a rigorous follow-up. The selection of investigators was open to all practitioners, some of whom may receive a financial interest in the completion of participating in a surveillance study. With this wide variety of investigators, there was variability in documentation, treatment and subjective language in medical record. Compliance with lens wear requirements was based on periodic reports by subjects. The classification of microbial keratitis was determined by clinical researchers who had direct communication with the investigator, but did not have direct contact with the patient or photographs.

The Study Strengths and Study Limitations should be considered when evaluating the significance of the results.

SELECTION OF PATIENTS

The eye care professional should fit, or provide lenses to, patients who cannot, or will not, adhere to a recommended care regimen, or regulators, or are unable to use and remove the lenses. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal abscess.

Patient communication is vital because it relates not only to patient selection but also to patient history and willingness. The wearing schedule should be determined by each individual patient, based upon a full examination and patient history as well as the advantages of clear near vision in straight ahead and upward gaze that may reduce visual acuity and depth perception for distance and near tasks. During glasses. Each patient should understand that monovision can create a vision compromise.

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Patients selected to wear Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet with the patient at the time of the initial examination.

Instructions for Use:

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

WARNING: Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh disinfecting solution to disinfect lenses. Use of non-sterile lens disinfecting solution can lead to severe infection, vision loss or blindness.

c. Water Activity Information:

Water can harm microorganisms that can cause severe infection, vision loss or blindness. If your lenses have been submerged in water when swimming in pools, lakes or oceans, rinse and replace with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing contact lenses during any activity involving water.

d. Discard Date on Solution Bottle

Instruct for Use: Discontinue solution when the discard date is reached or the remaining solution is not sterile. Replace lens case according to directions given by your eye care professional. Logically, the labeling that came with your case.

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

CARE FOR A STICKING (NONDEHYDRATED) LENS

If a lens sticks to the eye, the patient should be instructed to use a lubricating solution to rewet the lens in their eye. The patient should be instructed to not use plain water, soap, or saline solution. The patient should then place their eye lid open and contact the eye care professional if the lens does not begin to move after blinking several applications of the solution, and to not attempt to remove the lens except on the task itself.

CARE FOR A DRIED-OUT (DEHYDRATED) LENS

It is a soft, hydrophilic lens material is exposed to air for a while and, in the future, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply the recommended solution before handling.

To rehydrate the lens:
- Handle the lens carefully.
- Place the lens in its storage case and soak it in a recommended rewetting and storing solution for at least 1 hour before return to a soft state.
- Clean lens first; then disinfect the rehydrated lens using a recommended lens care solution.
- 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.

EMERGENCIES

If the lens is lost (inert, unmodified products, gardening solutions, laboratory chemicals) are splashed into your eyes, you should FLUSH EYES IMMEDIATELY. Have the patient immediately contact their eye care professional, CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL IMMEDIATELY.