DESCRIPTION
The Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lens is a soft, hydrophilic, continuously hydrated contact lens that provides a uniform level of hydration and facilitates protein drainage. The lens material, balafilcon A, is a copolymer of sulfone and vinyl alcohol, providing a balance of oxygen permeability and tear wetting characteristics. The lens features a unique hybrid ballasting design that results in excellent comfort and an elongated daily wear schedule. This makes the lens suitable for patients who require maximum performance and comfort in a contact lens. The product number for this lens is 203425-30.

CONTRAINdications
- Allergic reactions to the material or any of the ingredients of the lens
- Active corneal infection
- History of contact lens intolerance
- History of Acanthamoeba or other keratitis

WARNINGS
- Never use conventional hard contact lens solutions that are not also recommended for use in the contact lenses. Conventionally processed solutions do not contain the same preservatives as recommended solutions and may cause chemical injury to the corneal epithelium
- Be sure that before leaving the eye care professional’ s office, the patient is able to comfortably wear and tolerate the lens
- Be sure that before leaving the eye care professional’s office, the patient is able to comfortably wear and tolerate the lens
- Be sure that the patient is able to understand and follow the care regimen in order to maintain the lens hygiene

Solutions
- Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.
- The Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.
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How the Lens Works (Actions)
- The patient should be informed that the following problems may occur:
  - The lens may be prescribed for Frequent / Planned Disposable Wear
  - If a patient experiences eye discomfort, excessive tearing, vision changes, or any other symptoms not described in the leaflet, the patient should place the lens in the storage case and contact the eye care professional.
  - Always follow directions in the package inserts for the use of contact lens solutions and lens care products, as well as the manufacturer’s labeled lens care system.

Practitioner Fitting Sets
- The practitioner should be informed of the potential complications associated with the use of contact lenses.
- The practitioner should be informed of the potential complications associated with the use of contact lenses.
- The practitioner should be informed of the potential complications associated with the use of contact lenses.

Precautions
- Eye selection should be based on the patient’s visual acuity, tear production, and other factors.
- The patient should be informed of the potential complications associated with the use of contact lenses.
- The patient should be informed of the potential complications associated with the use of contact lenses.

ADVERSE REACTIONS
- Many patients will notice a slight increase in corneal sensitivity
- Sensitivity to light (photophobia)
- Eye discomfort (including burning, itching, or irritation)
- Eye pain
- Sensitivity to light (photophobia)
- Eye discomfort (including burning, itching, or irritation)
- Eye pain

TABLE OF CONTENTS
- Solution
- Approval
- Centres
- N.B.
- The lens is available in a variety of diameters and base curves. The patient should be informed of the potential complications associated with the use of contact lenses.
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IMPORTANT
- The package insert and fitting guide have been designed to improve patient care and provide accurate information. The information contained in the package insert and fitting guide is correct as of June 2013 and supersedes all prior fitting guides for the product. The patient should be informed of the potential complications associated with the use of contact lenses.
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DISPOSABLE WEAR
- If the discomfort or problem stops, the patient should look closely at the lens. If the discomfort or problem persists, the patient should immediately remove the lenses and consult the eye care professional.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or any other symptoms not described in the leaflet, the patient should place the lens in the storage case and contact the eye care professional.
- Always follow directions in the package inserts for the use of contact lens solutions and lens care products, as well as the manufacturer’s labeled lens care system.

Care for a Sticking (Nonmoving) Lens
- If a patient experiences eye discomfort, excessive tearing, vision changes, or any other symptoms not described in the leaflet, the patient should place the lens in the storage case and contact the eye care professional.
- Always follow directions in the package inserts for the use of contact lens solutions and lens care products, as well as the manufacturer’s labeled lens care system.
- The patient should be informed of the potential complications associated with the use of contact lenses.
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Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. It is optional to use fluorescein to check for abnormal corneal wettability.

How the Lens Works (Actions)
- The patient should be informed that the following problems may occur:
  - The lens may be prescribed for Frequent / Planned Disposable Wear
  - If a patient experiences eye discomfort, excessive tearing, vision changes, or any other symptoms not described in the leaflet, the patient should place the lens in the storage case and contact the eye care professional.
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The lens is available in a variety of diameters and base curves. The patient should be informed of the potential complications associated with the use of contact lenses.

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- Eye selection should be based on the patient’s visual acuity, tear production, and other factors.
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ADVERSE REACTIONS
- Many patients will notice a slight increase in corneal sensitivity
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- Eye discomfort (including burning, itching, or irritation)
- Eye pain
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- Eye discomfort (including burning, itching, or irritation)
- Eye pain

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Oxygen Permeability: \( 91 \times 10^{-11} \text{cm}^3 \text{O}_2 \text{(STP)} \times \text{cm} / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) \)

The physical/optical properties of the lens are:

- This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.
- Lens is a soft hydrophilic contact lens which is available as a flexible shell with a toric component (Ultracare Disinfecting Solution, Ultracare Neutralizing Lotion) or as a monovision design with a flat lens (balafilcon A) Visibility Tinted Contact Lens). The soft toric lens comes in the following description, lens prism, and cylinder powers.

### LENS PARAMETERS AVAILABLE

- **Sphere Power (Diopters)**
  - 6.25D
  - 7.25D
  - 8.25D
  - 9.25D
  - 10.25D
  - 11.25D
  - 12.25D
  - 13.25D
  - 14.25D
  - 15.25D

- **Cylinder Powers**: –0.75D, –1.25D, –1.75D, -2.25D and -2.75D

- **Diameter**: 14.5mm

- **Center thickness**: 0.12mm

- **Edges**: Graduated
d

- **Base curve**: 8.6

- **Stability**: Spherically curved

- **Clarity**: Aspheric

- **Color**: Blue

- **Storage Temperature**: +4°C to +25°C

- **Preservative**: No

- **Surface Treatment**: Performa™

- **Material**: Balafilcon A

- **Manufacturer**: Bausch + Lomb

- **Type**: Contact Lens

- **Usage**: 1-day, 1-week, 1-month, 1-year, 1-year

- **Quantity**: 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40

- **Supplementary Information**: Refer to the patient information booklet on the lens case manufacturer or eye care professional.

### HOW THE LENS ACTS (OPTIC)

In its hydrated state, the Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lens is a single use lens. 

- **Center of Intensity**: The center of intensity for the lens is the point where the light from the lens enters the eye. The center of intensity is located at the optical center of the lens.

- **Axis**: The axis of the lens is the line that passes through the center of the lens and the center of the cornea.

- **Spine**: The spine of the lens is the line that passes through the center of the lens and the center of the cornea.

- **Color Guide**: The color guide is the line that passes through the center of the lens and the center of the cornea.

### LENS PREREQUISITE

- **Corrective Power**: The corrective power of the lens is determined by the optical properties of the lens.

- **Sphere Power**: The sphere power of the lens is determined by the optical properties of the lens.

- **Cylinder Power**: The cylinder power of the lens is determined by the optical properties of the lens.

- **Axis**: The axis of the lens is determined by the optical properties of the lens.

### LENS RECOMMENDATIONS

- **Daily Use**: The lens is recommended for daily use.

- **Weekly Use**: The lens is recommended for weekly use.

- **Monthly Use**: The lens is recommended for monthly use.

- **Yearly Use**: The lens is recommended for yearly use.

### PRACTICAL CONSIDERATIONS

- **Temperature**: The temperature of the lens is determined by the optical properties of the lens.

- **Humidity**: The humidity of the lens is determined by the optical properties of the lens.

- **Light Source**: The light source is determined by the optical properties of the lens.

### ADVERSE REACTIONS

- **Redness of the eyes**: Redness of the eyes is determined by the optical properties of the lens.

- **Excessive watering (tearing)** of the eyes is determined by the optical properties of the lens.

- **Barrier to the eye**: A barrier to the eye is determined by the optical properties of the lens.

- **Demulcent**: A demulcent is determined by the optical properties of the lens.

- **Ointment**: An ointment is determined by the optical properties of the lens.

- **Other**: Other adverse reactions are determined by the optical properties of the lens.

### IMPORTANT

- **Temperature and humidity**: The temperature and humidity of the lens are determined by the optical properties of the lens.

- **Light source**: The light source is determined by the optical properties of the lens.

- **Barrier**: A barrier to the eye is determined by the optical properties of the lens.

- **Demulcent**: A demulcent is determined by the optical properties of the lens.

- **Ointment**: An ointment is determined by the optical properties of the lens.
Important treatment information for this atension:

CLINICAL STUDY

The following results were generated from a prospective, randomized, controlled trial called "Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lenses Comparison Study". The study was conducted between September 2007 and November 2008. The study was designed to assess the efficacy and safety of the Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lenses compared to a control lens for the correction of spherical and astigmatic refractive error.

The primary endpoint of the study was safety, as determined by the occurrence of grade 2 and higher complications, defined as any condition that might be occurring related to contact lens wear. If the patient is wearing a contact lens on one eye while the contralateral eye has a lens care solution or is a non-wearer, the patient should be included in the safety analysis for the contact lens wear eye. At the time of the first follow-up examination, the patient should be questioned regarding vocation, desired lens wearing time (full or part-time), and lens usage history.

Table 12: Summary of Complications

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>n (%)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral Lens Correction</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Contraction</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Conjunctivitis</td>
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<td>0.2</td>
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<tr>
<td>Abnormalities</td>
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<td>0.3</td>
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<tr>
<td>Superficial Keratitis</td>
<td>0.4</td>
<td>0.4</td>
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<tr>
<td>External Adnexa Abnormalities</td>
<td>0.5</td>
<td>0.5</td>
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<tr>
<td>Limbal Injection</td>
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<td>0.6</td>
</tr>
<tr>
<td>External Subconjunctival Hemorrhage</td>
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<td>0.7</td>
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<tr>
<td>External Conjunctival Hemorrhage</td>
<td>0.8</td>
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<tr>
<td>External Adnexa Abnormalities</td>
<td>0.9</td>
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<tr>
<td>External Contraction</td>
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<tr>
<td>External Adnexa Abnormalities</td>
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<td>1.1</td>
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<td>External Conjunctival Hemorrhage</td>
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<td>External Contraction</td>
<td>1.8</td>
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<td>External Adnexa Abnormalities</td>
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<td>1.9</td>
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<tr>
<td>External Conjunctival Hemorrhage</td>
<td>2.0</td>
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<td>External Adnexa Abnormalities</td>
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<tr>
<td>External Adnexa Abnormalities</td>
<td>2.9</td>
<td>2.9</td>
</tr>
<tr>
<td>External Contraction</td>
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<td>3.0</td>
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</table>

Endnotes:

1. *Centralized data management was conducted by Clinical Resources, Inc. This analysis used the graded slit lamp findings at the time of first follow-up examination.

**Bausch + Lomb PureVision®2 Toric (balafilcon A) Visibility Tinted Contact Lenses are intended to be used for the correction of spherical and astigmatic refractive error. They should be worn continuously for up to 30 days per lens, with a suggested daily wear schedule of 14 hours. The lenses should not be worn more than 30 days per lens. The lenses are intended to be worn by adults and children 12 years of age and older.

6. Characteristics of a Loose (Flat) Lens

a. The lens may be felt flatter than the fit is over.

b. The lens may be difficult to see. It may be necessary to remove the lens and then replace it to confirm the flattening.

c. The lens may not remain stationary when the patient is looking downward. The lens may move upward or downward as the eye blinks.

d. The lens may not remain steady in a line of vision. The lens may roll or shift side to side.

e. The lens may not remain steady in a direction of gaze. The lens may shift in a direction of gaze.

7. Other Suggestions

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a lens care solution, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

c. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

d. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

8. EMERGENCIES

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

9. HOW SUPPLIED

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

10. REPORTING OF ADVERSE REACTIONS

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

11. Care for the Contact Lens

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

12. Handling of the Contacts

a. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

b. If the patient is wearing a contact lens on one eye while the contralateral eye is wearing a non-wearing contact, the patient should be provided with a contact lens one eye prescription to wear.

13. The patient should be educated about the proper care and handling of the contact lenses.

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15. Any patient should be educated about the proper care and handling of the contact lenses.

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30. Any patient should be educated about the proper care and handling of the contact lenses.

31. Any patient should be educated about the proper care and handling of the contact lenses.
Fitting Procedure

A fitting history and measurement can increase your chances:

- Make sure all measurements are correct for the eyes you are intentioned.
- Make sure the refraction results are consistent and repeatable.
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