

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted 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 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 14609

© Bausch & Lomb Incorporated. All rights reserved worldwide.

Bausch & Lomb and PureVision are trademarks of Bausch & Lomb Incorporated.

Covered by and/or licensed under one or more of the following U.S. Patents: 5610252, 4997897, 5815239, 5760100, 5789461, 5849811, 5766999, 5965631 and other patents.

Printed in U.S.A.

3/05