

PACKAGE INSERT

for the
Performance Vision Technologies, Inc.

Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION

The Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses are fabricated from ocufilcon D, which is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid (MAA), cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% ocufilcon D and 55% water by weight when immersed in saline solution.

The Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses are subsequently tinted to achieve different colors using listed color additives (21 CFR Part 73). The lenses are processed to incorporate the color additives and contain only the amount of the additive needed to accomplish the intended coloring effect. The lenses contain one or a combination of one or more of the following color additives: Reactive Black 5, Reactive yellow 15, Reactive orange 78, Reactive red 180.

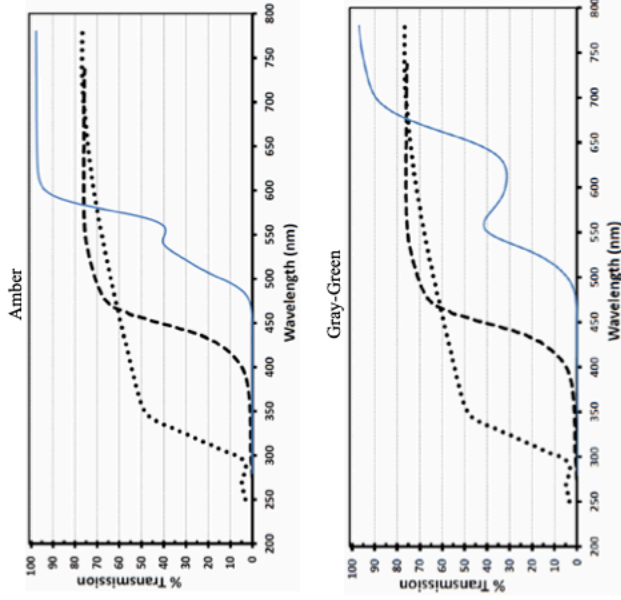
The Altius™ (ocufilcon D) Performance-Tinted Contact Lenses are designed to aid visual performance in athletic and other performance settings. Altius™ (ocufilcon D) Performance Tinted Contact Lenses enhance contrast in a wide range of light conditions. This enables the wearer to see a ball or selected objects with greater clarity than with the naked eye.

Altius™ (ocufilcon D) contact lens properties and parameters:

Parameter	Range	Tolerance*
Chord Diameter	14.20 mm	±0.20 mm
Center Thickness	0.05 to 0.15 mm	When ≤0.10 mm → ±0.010 mm + 10% When >0.10 mm → ±0.015 mm + 5%
Base Curve	8.70 mm	±0.20 mm
Back Vertex Power (F ^v)	+20.00D to -20.00D (0.25D steps)	When 0.00 < F ^v ≤10.00 D → ±0.25 D When 10.00 < F ^v ≤20.00 D → ±0.50 D
Surface Appearance	-	Lenses should be clear, no surface defect
Oxygen Permeability (x 10 ⁻¹⁰ (cm ² /sec)(mO ₂)/(ml x mmHg))	19.6	±20%
Light Transmission - Tinted (@ 390-780nm)	>30%	±5%
Ultraviolet Radiation Transmittance	<5 % T _{UVB} <50 % T _{UVA}	T _{UVB (280 to 315 nm)} <0.05T _v T _{UVA (316 to 380 nm)} <0.50T _v
Water Content	55%	±2%
Refractive Index	1.410 (hydrated)	±0.005

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties (2010)

Refer to the following transmittance profile for the Altius™ (ocufilcon D) Performance-Tinted Contact Lenses (solid line), as well as a human cornea (dotted line) and a human lens (dashed line):



Note: the above % transmission data are based on measurements from -3.00 D lenses. The data was obtained from measurements with a spectrophotometer taken through the central 5-5 mm portion of the Altius™ (ocufilcon D) contact lens.

The Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses incorporate a UV absorbing monomer. The lenses block >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (316nm - 380nm).

Note: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities), UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

ACTIONS

In its hydrated state, the Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

CAUTION

Clinical studies have demonstrated that ocufilcon D contact lenses are safe and effective for their intended use; however, due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, designs, or lens parameters available in the lens material are not evaluated in significant numbers. When selecting an appropriate lens design and parameters, 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 potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. The continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye-care practitioner.

INDICATIONS

The Altius™ (ocufilcon D) Performance-Tinted SPHERICAL contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased that may exhibit astigmatism up to 2.0 diopters that does not interfere with visual acuity.

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses when any of the following conditions are present:

- 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 hyposthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens.
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.
- Multi-purpose solution is not to be used with Daily Disposable lenses at any time.
- All contact lens wearers must see their eye-care practitioner as directed.

VISIBLE LIGHT REDUCTION: Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses reduce light transmission into the eye in certain wavelength ranges of the visible spectrum and may alter color perception, similar to tinted sunglasses. Unlike sunglasses, contact lenses cannot be removed quickly and easily when complete, normal vision is essential. Patients should NOT wear Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses in any of the following circumstances:

- In dimly lit environments (e.g., nighttime).
- While operating a motor vehicle or other heavy machinery.
- In other situations where safety is compromised without accurate color vision.

AT ALL TIMES, Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lens wearers should have a pair of general use contact lenses, glasses, or sunglasses available in case environmental or safety conditions change that require removal of the Altius™ Contact Lenses.

Water Activity – Instruction for Use: Do not expose the contact lenses to water while wearing them.

WARNING: Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submerged in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. The patient should ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION IF THE PATIENT EXPERIENCES:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Eye Redness
- Or Other Eye Problems

THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

PRECAUTIONS

- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorbs this dye and becomes discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.
- Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.
- If the lens gets dehydrated or is exposed to dust, a foreign body or other contaminant, the lens should be removed and replaced with a new lens.
- Carefully follow the instructions for use in the patient instructions for the Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses and those prescribed by the eyecare practitioner.
- Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Never wear lens beyond the period recommended by the eyecare practitioner.
- Water activity: the Patient should not expose their contact lenses to water while wearing them.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask the eyecare practitioner about wearing lens during sporting activities.
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine or medications in the eyes.
- Always inform a health care provider or employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed 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.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- Unusual eye secretions.
- Redness of the eye.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

If the patient notices any of the above, instruct the patient to IMMEDIATELY REMOVE AND DISCARD LENS. If the problem continues, the patient should IMMEDIATELY REMOVE THE LENS AND CONSULT THE EYECARE PRACTITIONER.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

FITTING

For a detailed description of the fitting techniques, refer to *Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses Professional Fitting and Information Guide*, copies of which are available from:

Performance Vision Technologies, Inc.

www.Altiusvision.com
email: info@Altiusvision.com

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to over wear the lens initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important. The Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses are single use.

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT ALTIUS™ (OCUFILCON D) SOFT (HYDROPHILIC) CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

LENS CARE DIRECTIONS

When lenses are dispensed, the patient should be provided with adequate instructions and warnings for lens care handling. For complete information and instruction refer to *Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses Daily Disposable Patient Instruction/Wearer's Guide*.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eyecare practitioner.

HOW SUPPLIED

The Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses are sterile in sealed blister packages containing a buffered saline solution with HPMC and poloxamer. The base of the package is made from

polypropylene, which is covered with an aluminum foil seal on top. The blister packages are marked with the base curve, diameter, dioptric power, lens color, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Altius™ (ocufilcon D) Performance-Tinted Soft (Hydrophilic) Daily Wear Contact Lenses or experienced with the lens should be reported to:

Performance Vision Technologies, Inc.

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