











PROFESSIONAL FITTING AND INFORMATION GUIDE

ProOcular Daily Disposable Contact Lenses

IMPORTANT: Please read carefully and keep this information for future use. This document is intended for the Eye Care Professional. The Eye Care Professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

The following symbols may appear on the label or carton

Symbol	Definition
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat
	Manufacturer
	Do Not Reuse
	Quality System Certification Symbol
	Package material and recycling symbol
	Lens contains UV blocking monomer
PWR	Power (in diopters) for contact lens
BC	Base Curve
DIA	Diameter
D	Diopter (lens power)

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

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1. GLOSSARY OF TERMS

Words that are explained below are identified at each occurrence in the text by highlighting with bolding.

Terms	Definition
Adnexa	Tissue surrounding the eyeball.
Ametropia (myopia)	Nearsightedness. A condition where the eyeball is too long and steep, so that light rays focus before they reach the retina. The result is difficulty in seeing distant objects clearly.
Anterior chamber	The anterior chamber (AC) is the fluid-filled space inside the eye between the iris and the Cornea's innermost surface.
Aphakic	Absence of the crystalline lens of the eye.
Aspheric lens / Asphere	Contact Lens with its front or back optic zone of aspheric form.
Astigmatism	A condition where the Cornea is irregularly shaped, causing distorted vision especially at near distances.
Conjunctiva	The membrane lines the inside of the eyelids and covers the sclera (white part of the eye).
Cornea	The Cornea is the transparent front part of the eye that covers the iris, pupil, and anterior chamber.
Corneal ulcer	A Corneal ulcer is an open sore or lesion on the Cornea.
Daily wear	Worn during waking hours and removed at the end of each day for cleaning and disinfecting.
Disinfection	A process that kills harmful microorganism (germs) which can cause serious eye infection.
Light Transmittance	The clearness (clarity) of a material; denoted as a percentage of incident light passing through a sample of the material.
Oxygen Permeability (Dk)	The amount of oxygen diffusing through a given amount of lens material in a given amount of time, under specified testing conditions.
Refractive Index	The ratio of the speed of light in air to the speed of light in the specified material. Lens materials with a higher index can be made thinner yet provide the same prescription.
Iritis	Inflammation of the colored part of the eye (Iris).
Neovascularization	Blood vessel growing into the Cornea.
Subacute inflammation	Gradual swelling, redness and pain.
Ulcerative Keratitis	An infected Corneal ulcer.
UV (ultraviolet)	Light from the sun that can be harmful to the eye.
Water content	The percentage volume of water in a lens material by weight; also known as hydration.

2. DESCRIPTION

ProOcular Daily Disposable Contact Lenses is available as **aspheric lens** design.

The lens material, Polymacon, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA) crosslinked with ethylene glycol dimethacrylate (EGDMA). The lenses are tinted blue for visibility purposes with the color additive, C.I. Reactive Blue No. 4. The lenses contain a benzophenone UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light. The average transmittance characteristics are less than 5 % in the UVB range of 280 to 315 nm and less than 50 % in the UVA range of 316 to 380 nm. The lenses are available as aspheric lenses. Each finished lens is supplied in a plastic blister container with a sterile isotonic phosphate buffered saline solution containing 0.01 % sodium hyaluronate and 0.1 % trehalose wetting agents.

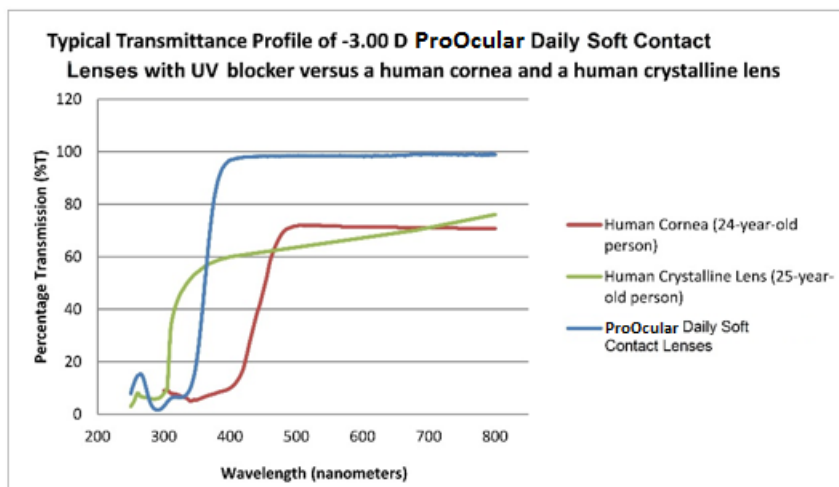
ProOcular Daily Disposable Contact Lenses are hemispherical shells of the following parameters:

- Diameter: 12.00 ~ 15.00 ± 0.20 mm
- Basic Curve: 7.85 ~ 10.00 ± 0.20 mm
- Center Thickness: 0.06 mm ± 0.02 mm
- Powers: -1.00 D to -10.00 D

The physical/optical properties of the lens are:

- Refractive Index: 1.440 ± 0.005 n_d
- Light Transmittance: > 95 %
- Surface Character: Hydrophilic
- Water Content: 38 %
- UV transmittance: UVB < 5 %, UVA < 50 %
- Oxygen Permeability (Dk)* : 13.5 ± 20 % x 10⁻¹¹

*(cm²/sec)(ml O₂/ml x mmHg) 35°C (Polarographic method for determination of oxygen permeability)



1. Human cornea from a 24 year-old person as described in Lerman, S., Radiant Energy and the Eye, New York, 1980, p. 58, Figure 2-21.
2. Human crystalline lens from a 25 year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.
3. The UV lenses (ProOcular Daily Disposable Contact Lenses).

* The data was obtained from measurements taken through the central 3-5 mm portion of the thinnest

marketed version of the UV lens (-3.00 D, 0.060 mm center thickness) and measured according to ISO 18369-3:2006 – Ophthalmic optical – Contact Lenses – Part 3: Measurement methods.

WARNING: 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.

3. ACTIONS

When placed on the **cornea** in its hydrated state, ProOcular Daily Disposable Contact Lenses act as refracting media to focus light rays on the retina. The UV absorbing monomer in ProOcular Daily Disposable Contact Lenses is used to block UV radiation. The average transmittance characteristics are less than 5 % in the UVB and less than 50 % in the UVA.

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as 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 Professional for more information.

4. INDICATIONS FOR USE

The ProOcular Daily Disposable Contact Lenses is indicated for daily wear single use only for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal: Therefore no cleaning or disinfecting is required. The ProOcular Daily Disposable Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

5. CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use the ProOcular Daily Disposable 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 insufficiency of lacrimal secretion (dry eyes).
- **Corneal** hypoesthesia (reduced **corneal** sensitivity), if not **aphakic**.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or **adnexa** 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 ProOcular Daily Disposable Contact Lenses.
- Any active **corneal** infection (bacterial, fungal, or viral).
- If eyes become red or irritated.

6. WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including **corneal ulcers**, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of **ulcerative keratitis** is greater for extended wear contact lens users than for daily wear users.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of **ulcerative keratitis** is greater than among those who do not wear them overnight.
- The overall risk of **ulcerative keratitis** may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of **ulcerative keratitis** among contact lens users who smoke is greater than among non-smokers.
- If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

7. PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, 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 potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear aspheric contact lenses, such as ProOcular Daily Disposable Contact Lenses, 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.
- Eye Care Professional should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the Eye Care Professional.
- 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.

- Aphakic patients should not be fitted with ProOcular Daily Disposable Contact Lenses until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear, and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct frequent replacement lens wear patients about the following care regimen and safety 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.
- Be sure that before leaving the Eye Care Professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Information Booklet for the ProOcular Daily Disposable Contact Lenses and those prescribed by the Eye Care Professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

8. ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- 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, he or she should be instructed to:

- **IMMEDIATELY REMOVE THEIR LENSES.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the 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, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PROFESSIONAL.**

When any of the above problems occur, a serious condition such as infection, **corneal ulcer**, **neovascularization**, or **iritis** may be present. The patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PROFESSIONAL.** The patient should bring their lenses, solutions and lens case with them to their eye care provider for culturing in order to better establish the identity of any organism associated with the patient's infection.

9. SELECTION OF PATIENTS

The Eye Care Professional should not fit patients who cannot or will not adhere to the replacement regimen for ProOcular Daily Disposable Contact Lenses or are unable to place and remove the lenses should not be provided with them.

Failure to follow handling instructions could lead to serious eye infections which might result in **corneal ulcers**.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Package Insert with the patient at the time of the initial examination.

Patients selected to wear ProOcular Daily Disposable Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The Eye Care Professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow the Eye Care Professional instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination. It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact his or her Eye Care Professional.

10. FITTING SUMMARY

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive should be discussed with the patient prior to dispensing.

11. LENS REPLACEMENT / WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Professional. Patients tend to over-wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional are also extremely important.

Studies have not been conducted to show that **ProOcular Daily Disposable Contact Lenses** are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period.

ProOcular Daily Disposable Contact Lenses indicated for daily wear. The maximum suggested wearing time for the lenses is:

Day	Hours
1	4
2	6
3	8
4	10
5	12
6 and after-	all waking hours

12. WATER ACTIVITIES

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 submersed in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

13. LENS CARE DIRECTIONS

- ProOcular Daily Disposable Contact Lenses are prescribed for daily disposable wear, and are to be discarded after each removal. The Eye Care Professional should review lens care directions, including both basic lens care information and specific instructions on the daily disposable lens care regimen with the patient. You should have a spare pair of lenses with you at all times.
- Basic Instructions
 - Always wash, rinse, and dry hands before handling contact lenses.
 - Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
 - Lenses should be thrown away after they are removed from the eye after the recommended wearing time prescribed by the Eye Care Professional.
 - Eye Care Professional may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
 - Recommended Temperature Storage Range: 46° to 86°.

14. CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

15. CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3

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 non-movement of the lens continues more than 5 minutes, the patient should immediately consult the Eye Care Professional.

16. EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

17. HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER PACK IS BROKEN OR THE SEAL HAS BEEN DAMAGED

18. REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing any contact lens or experienced with the lenses should be reported to:

Comfort Vision
5928 Farnsworth Court, Carlsbad, CA 92008
Toll-Free Telephone Number: 1-855-397-9777
www.comfort-vision.com

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