

PATIENT INSTRUCTION GUIDE

ProOcular Daily Disposable Contact Lenses

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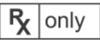
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GLOSSARY OF TERMS

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).
Conjunctivitis	Inflammation of the conjunctiva.
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.
Iritis	Inflammation of the colored part of the eye (Iris).
Neovascularization	Blood vessel growing into the cornea.
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances (loss of reading vision). Usually becomes significant after age 45.
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.

SYMBOL REFERENCE GUIDE

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.

INTRODUCTION

The instructions in this booklet apply to the ProOcular Daily Disposable Contact Lenses. For ProOcular Daily Disposable Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care professional answer any questions, both before and after you receive contact lenses.

Please refer to the Glossary of Terms for definitions of medical/technical terminology used in this booklet. In addition, the Symbols Key provides an explanation of symbols that may appear on the lens packaging.

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history and will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging.

You should read the sections of this booklet entitled “Warnings”, “Adverse Reactions”, “Precautions”, and “Wearing Restrictions and Indications”. Ask your Eye Care Professional to explain anything that you do not understand, including any additional restrictions which may be given to you by your Eye Care Professional.

You will also be taught how to properly apply and remove lenses. This booklet will reinforce those instructions.

If you have any questions, please ask your Eye Care Professional.

WEARING RESTRICTIONS AND INDICATIONS

The ProOcular Daily Disposable Contact Lenses is indicated for the correction of ametropia (myopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -1.00 to -10.00 diopters. The lenses may be worn by persons 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.

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.

WARNINGS

You should be aware of and fully discuss with your Eye Care Professional the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to your eye. You should know 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 contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- You should know that when you wear your daily wear 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.
- If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, **YOU SHOULD IMMEDIATELY REMOVE YOUR LENSES AND**

PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

- It is recommended that you see your Eye Care Professional routinely as directed.

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.

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.

PRECAUTIONS

Handling Precautions:

- **DO NOT** use if the sterile blister package is opened or damaged.
- Before leaving the Eye Care Professional's office, you should be able to quickly remove your lenses or you should have someone else available who can remove the lenses for you.
- **Always wash and rinse your hands before handling your lenses.** Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- **DO NOT** touch your contact lenses with your fingers or hands if they are not completely clean, because tiny lens scratches may occur, causing unclear vision and/or injury to your eye.
- **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.
- **Always** handle lenses carefully and avoid dropping them.
- **Never** use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- **Do not** touch the lens with your fingernails.

Lens Wearing Precautions:

- You should remove your lenses immediately if your eyes become red or irritated.

- **Never** wear your lenses beyond the amount of time recommended by your Eye Care Professional.
- If aerosol (spray) products, such as hair spray, are used while wearing lenses, exercise caution and **keep your eyes closed** until the spray has settled.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
- **Ask** your Eye Care Professional about wearing contact lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub **may increase the risk of eye infection** from germs.
- **Always throw away** lenses worn as prescribed by your Eye Care Professional.

Lens Care Precautions:

- The Eye Care Professional should review with the patient that no cleaning or disinfecting is needed with daily wear single use lenses. Patients should dispose of lenses when they are removed and have replacement lenses or spectacles available .Other Topics to discuss with Your Eye Care Professional:
- **Always** contact your Eye Care Professional before using any medicine in your eyes.
- **Be aware** that if you use oral contraceptives (birth control pills), you could develop changes in vision or comfort when wearing contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

Who Should Know That You are Wearing Contact Lenses:

- **Inform** your doctor (Healthcare Professional) about being a contact lens wearer.
- **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

You should be aware 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.
- Abnormal feeling of something in the eye (foreign body, 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 you notice any of the above:

- Immediately remove your lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT PUT THE LENS BACK ON THE EYE**. Place the lens in the storage case and contact your 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, you should thoroughly clean, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues, you 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. You should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PROFESSIONAL**. You should bring your lenses, solutions and lens case with you to your eye care provider for culturing in order to better establish the identity of any organism associated with your infection.

PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with

fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mixups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.
 - a. Less than usual comfort.
 - b. The lens may fold on the eye.
 - c. Excessive lens movement on blink.
 - d. Blurred vision.
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution.
- If this gentle rubbing does not work, soak the lens in the recommended solution in your lens case until the lens has resumed its normal shape. If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.
- Keep the lens wet in the solution recommended by your Eye Care Professional.
- Never place a lens on the eye unless it has been fully hydrated (wet) with the recommended rinsing or storing solution.

3. Placing the Lens on the Eye:

There are other methods of lens placement. If the following methods are difficult for you, your Eye Care Professional will provide you with an alternate method.

Remember, always start with the same eye.

Once you have opened the lens package, removed and examined the lens, follow these steps to apply the lens to your eye:

- (1) Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.
- (2) Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.
- (3) Use the index finger or middle finger of the other hand to lift the upper lid.

- (4) Place the lens on the eye.
- (5) Gently release the lids and blink. The lens will center automatically.
- (6) Use the same technique when inserting the lens for your other eye.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

4. Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

5. Removing the Lens:

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, LENS CARE DIRECTIONS.

Note: If this method of removing your lens is difficult for you, your Eye Care Professional will provide you with an alternate method.

WATER ACTIVITIES

Instruction for Use:

Do not expose your contact lenses to water while you are wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you 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.

LENS CARE DIRECTIONS

ProOcular Daily Disposable Contact Lenses are prescribed for daily disposable wear, and are to be discarded after each removal. Your 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 you. You should have a spare pair of lenses with you at all times.

1. 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 practitioner.
- 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°.

2. Care for a Sticking (nonmoving) Lens:

If the lens sticks (stops moving or cannot be removed), you should 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, you should immediately consult the Eye Care Professional.

3. 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.

4. EMERGENCIES:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: **FLUSH EYES WITH TAP WATER AND**

IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING AND APPOINTMENT SCHEDULES

Prescribed Wearing Schedule

DAY	DATE	WEARING TIME(HOURS)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		

EYE CARE PROFESSIONAL INFORMATION

PLEASE FILL OUT FOR READY USE

Name:

Address:

Phone:

Other Information:

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, **DO NOT WAIT** for your next appointment.

CONTACT YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

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