

PERMALENS®
PERMALENS® THERAPEUTIC
PERMALENS® APHAKIC
(perfilcon A)
HYDROPHILIC CONTACT LENSES

PACKAGE INSERT

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION: Federal (US) Law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION:

The perfilcon A soft (hydrophilic) contact lenses are available as spherical lenses. The lens material, perfilcon A is terpolymer of 2-hydroxyethyl methacrylate, N-vinyl-2-pyrrolidone and methacrylic acid, with ethylene glycol dimethacrylate as the cross linking agent for **Permalens, Permalens Therapeutic, and Permalens Aphakic.**

All perfilcon A soft (hydrophilic) contact lenses are hemispherical shells with the following dimensions:

Permalens® Product	Diameter (mm)	Base Curve (mm)	Center Thickness	Power (D)
Permalens (non-aphakic)	13.5-14.2	7.7-8.6	0.10-0.40	+8.00 to -20.00
Permalens Therapeutic	13.5-15.0	7.7-9.0	0.24	-20.00 to +20.00
Permalens Aphakic	14.0-14.5	8.0-8.9	0.26-0.52	Plano to +20.00

The physical/optical properties of the lenses are:

- Refractive Index: 1.38
- Surface Character: Hydrophilic
- Water Content: 71%
- Oxygen Permeability: $42.0 \times 10^{-11}(\text{cm}^2/\text{sec})$ (ml O₂/ml x mmHg) at 35°C (The method of Irving Fatt, Ph.D.)
- Light Transmittance: >96%

ACTIONS:

When placed on the cornea, the hydrated **Permalens** and **Permalens Aphakic** (perfilcon A) soft (hydrophilic) contact lens acts as a refracting medium to focus light rays on the retina.

Permalens Therapeutic (perfilcon A) soft (hydrophilic) contact lens acts as a bandage (membrane) to protect the cornea. When the patient needs improved visual acuity while the eye is healing, the lens with power acts as a refracting medium.

INDICATIONS (Uses):

The **Permalens** and **Permalens Therapeutic** soft (hydrophilic) contact lenses are indicated for extended wear from **1 to 7 days** between removals for cleaning and disinfection as recommended by the eyecare practitioner. They are indicated for the correction of hyperopia in **not-aphakic** persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Additionally, the **Permalens Therapeutic** soft (hydrophilic) contact lens is indicated to treat:

- Bulbous keratopathy
- Post-surgical conditions resulting from cataract extraction, corneal surgery, conjunctival surgery, and surgery to treat trauma
- Corneal dystrophy's
- Edema
- Injuries
- Ulcers
- Keratitis and corneal exposure
- Refractive amblyopia
- Other therapeutic indications not correctable with spectacles or conventional contact lenses

Note: **Permalens Therapeutic (perfilcon A) soft (hydrophilic) contact lens is not to be fitted solely to correct vision.**

The **Permalens Aphakic** (perfilcon A) soft (hydrophilic) contact lens is indicated for extended wear from **1 to 30 days** between removals for cleaning and disinfecting as recommended by the eyecare practitioner. They are indicated for the correction of hyperopia in **aphakic** persons with non-diseased eyes who have had cataract surgery. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. Supplemental spectacles may be required, in some conditions, to provide near or to compensate for uncorrected refractive astigmatism of greater than 2.00 diopters.

All perfilcon A soft (hydrophilic) contact lenses may be disinfected using a heat or chemical disinfection system.

CONTRAINDICATIONS:

DO NOT USE the perfilcon soft (hydrophilic) contact lens when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, which affects the cornea or conjunctiva.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- 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 perfilcon A lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- If eye becomes red or irritated.
- Patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS:

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

- Problems with contact lens wear and lens care products could result in serious injury to the eye. It is essential that patients follow their eyecare practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- If a patient experiences eye **discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the lenses** and promptly contact his or her eyecare practitioner.
- **The risk of ulcerative keratitis has been shown to be greater among user of extended wear lenses than among users of daily wear lenses. The risk among extended wear users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use.** This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- All contact lens wearers must see their eyecare practitioner as directed. If the lenses are for extended wear, the eyecare practitioner may prescribe more frequent visits.

PRECAUTIONS:

Special Precautions for Eyecare Practitioners:

- Due to the small number of patients enrolled in clinical investigations 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 eyecare practitioner should consider all characteristics of the lens that can affect 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 the eye should be carefully monitored by the prescribing eyecare practitioner.
- Aphakic patients should not be fitted with Permalens Aphakic soft (hydrophilic) contact lenses until the determination is made that the eye has healed completely.
- 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 the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eyecare practitioner's office, the patient should be able to remove or have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solution cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Never use solutions recommended for conventional hard contact lenses only.
 - Chemical disinfection solutions should not be used with heat unless specifically indicate on product labeling for use in both heat and chemical disinfection.
- Always use **fresh unexpired** lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (dehydrated) Lens if the lens surface does become dried out.
- To prevent contamination and to help avoid serious eye injury, always empty and rinse lens case with fresh, sterile rinsing solution and allow to air dry.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care of a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- 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 the lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-based products.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Instructions for perfilcon A soft (hydrophilic) contact lenses and those prescribed by the eyecare practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove the lenses 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 in the eye.
- Always inform the 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 lenses.
- 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 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 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 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 a storage case and contact the eyecare practitioner. 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 the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eyecare practitioner.**

When any of the above problems occur, a serious condition such as an 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.

For Therapeutic Use: Adverse affects may be due to progressions of the original disease or injury, or they may be due to the effects of wearing a contact lens.

Disease of injury-related problems: The eyecare practitioner should discuss with the patient the possibility that the existing disease or condition might become worse when the **Permalens** soft (hydrophilic) contact lenses for therapeutic use is used to treat already diseased or damaged eye.

The patient must be instructed to avoid serious eye damage by contacting his eyecare practitioner **IMMEDIATELY** if there is an increase in symptoms while wearing the lens. Possible problems include; edema, corneal ulcers, infections, infiltrates, iritis, neovascularization, ocular pain, and staining.

What to do if problem occurs: Contact the eyecare practitioner immediately if you have been told not to handle the lens.

If you have been taught how to handle your lens, do the following: Follow the procedure outlined above.

FITTING:

Conventional methods of fitting contact lenses apply to all **Permalens** (perfilcon A) soft (hydrophilic) contact lenses. For a detailed description of the fitting techniques, refer to the Permalens Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546
1-800-341-2020
www.coopervision.com

WEARING SCHEDULE:

The wearing and replacement schedules should be determined by the eyecare practitioner. Patients tend to overwear the lenses 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 PERMALENS AND PERMALENS THERAPEUTIC SOFT (HYDROPHILIC) CONTACT LENSES MUST BE REMOVED FOR CLEANING, RINSING, AND DISINFECTING AT LEAST ONCE EVERY 7 DAYS OR AS OFTEN AS RECOMMENDED BY THE EYECARE PRACTITIONER.

FOR THERAPEUTIC USE: The **Permalens** soft (hydrophilic) contact lens for therapeutic use can be worn as a protective (bandage) lens either on extended wear (24 hour) or shorter periods, as directed by the eyecare practitioner. The practitioner should closely follow the progress of the patients fitting with the therapeutic lens. The frequency of removal of the lens depends on the eyecare practitioner's recommendation.

PERMALENS APHAKIC SOFT (HYDROPHILIC) CONTACT LENS MUST BE REMOVED FOR CLEANING, RINSING, AND DISINFECTING AT LEAST ONCE EVERY 30 DAYS OR AS OFTEN AS RECOMMENDED BY THE EYECARE PRACTITIONER.

CAUTION: Not every patient is able to wear perfilcon A lenses on an extended wear basis even if the same patient is able to wear a contact lens on a daily wear basis. The eyecare practitioner will determine the wearing schedule that is best for the patient. Clinical studies have shown that a wearer's eyes adapt readily to wearing perfilcon A soft (hydrophilic) contact lens on an extended wear basis, and the limited initial wear is not usually necessary. However, the eyecare practitioner may recommend a limited wearing time. Remember, extended wear with any perfilcon A soft (hydrophilic) contact lens is not an endurance contest. Use good judgment, remove, clean, and disinfect the lenses anytime you notice a change in comfort, vision, or redness of your eyes.

LENS CARE DIRECTIONS:

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient. Carefully read the Instructions for Wearers booklet for details. Copies are available from the eyecare practitioner.

GENERAL LENS CARE (TO FIRST CLEAN AND RINSE, THEN DISINFECT LENSES)

Basic Instructions

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- 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 **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner), and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- The eyecare practitioner should recommend a care system that is appropriate for **Permalens** soft (hydrophilic) contact lenses.

LENS CARE TABLE	
Purpose To:	Product Chemical Lens Care System
Clean	Renu® Multi-Purpose Solution, Miraflow® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner
Rinse	Renu® Multi-Purpose Solution, SoftWear® Saline, Opti-Free® Rinsing, Disinfecting, and Storage Solution
Disinfect	Renu® Multi-Purpose Solution, AOSEPT® Disinfection/Neutralizing Solution, Opti-Free® Rinsing, Disinfecting, and Storage Solution
Store	Renu® Multi-Purpose Solution, Opti-Free Rinsing, Disinfecting, and Storage Solution
Lubricating & Rewetting	Renu® Rewetting Drops, CIBA Vision™ Lens Drops, Opti-Free® Rewetting Drops
Enzyme	Renu® Effervescent Enzymatic Cleaner Tablets, ULTAZYME® Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner

Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- **Clean** one lens first (always the same lens first to avoid mix-up), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the eyecare practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer, then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

HEAT (THERMAL) DISINFECTION:

- Prepare the empty lens storage case by filling the lens chambers with the solution which the eyecare practitioner has recommended to keep the lenses wet during disinfection.
- **After cleaning**, thoroughly rinse contact lenses with recommended solutions. **To keep the lenses wet during disinfection**, use the solution that is recommended by the lens manufacturer and/or eyecare practitioner.

- Put each lens into its correct chamber.
- Fill the chamber of the lens case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top of each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it is working, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eyecare practitioner recommends rinsing.
- Lens cases should be emptied, cleaned, and allowed to air dry.

CHEMICAL (NOT HEAT) DISINFECTION:

- Clean the contact lens with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning**, to disinfect, carefully follow the instructions accompanying the disinfection solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be **neutralized** before wearing. Follow the instructions on the disinfection solution labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Lens cases should be emptied, cleaned, and allowed to air dry.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- If the lenses have been stored in the unopened case or more than 24 hours, disinfect immediately before wearing or at least once a week.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. The lens case should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

CARE FOR A DRIED OT (DEHYDRATED) LENS:

If your perfilcon A soft (hydrophilic) contact lens is off your eye and exposed to air for 30 minutes or longer, it will become dry and brittle.

To rewet your lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in the recommended rinsing and storage solution **for at least two hours**. Soak the lens until it returns to a soft state.
- Clean and disinfect the **rewetted** (dehydrated) lens using the lens care system recommended by the eyecare practitioner.
- If after soaking, the lens does not become soft, **DO NOT USE THE LENS**, but contact the eyecare practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving or cannot be removed) on the eye, the patient should be instructed to apply 2-3 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 after 5-10 minutes, you should **immediately** consult the eyecare practitioner.

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 EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile buffered isotonic saline solution. The glass vial is marked with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date.

DO NOT USE IF THE GLASS VIAL OR CRIMP SEAL IS DAMAGED OR BROKEN

REPORTING OF ASVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing **Permalens** soft (hydrophilic) contact lenses or experienced or experienced with the lenses should be reported to:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Product Services
1-800-341-2020
www.coopervision.com

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