PERMALENS®

PERMALENS® THERAPEUTIC PERMALENS® APHASIC

(perfílcon 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 lenses.

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 Aphasic.

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

- Permalens® Diameter (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.
- Permalens® Therapeutic soft (hydrophilic) contact lenses are indicated for extended wear, the eye is healing, the lens power acts as a refracting medium.
- Permalens Aphasic soft (hydrophilic) contact lens acts as a refracting medium to focus light rays on the retina.

The physical/optical properties of the lenses are:
- Refractive Index: 1.38
- Surface Character: Hydrophilic
- Water Content: 71%
- Oxygen Permeability: 42.0 x 10^{-11} (cm^3/sec) (ml O_2/mmHg) at 80°C. (The method of Irving Fatt, Ph.D.)
- Light Transmittance: >96%

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 near-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that is not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

The Concomitant Use of Contact Lens Solutions:
- The physical/optical properties of the lenses are:
  - Refractive Index: 1.38
  - Surface Character: Hydrophilic
  - Water Content: 71%
  - Oxygen Permeability: 42.0 x 10^{-11} (cm^3/sec) (ml O_2/mmHg) at 80°C. (The method of Irving Fatt, Ph.D.)
  - Light Transmittance: >96%

ACTIONS:
When placed on the cornea, the hydrated Permalens and Permalens Therapeutic 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 is able to follow care regimen, the eye is healing, the lens 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 near-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that is not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

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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 eye injury.
- Always contact the eyecare practitioner in the event of injuries or problems related to contact lens wear.
- The contact lens is not designed to be used in water for swimming or contact lens care instructions in the Patient Package Insert for perfilcon A soft (hydrophilic) contact lenses must be followed to avoid serious eye damage.

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 to a recommended follow up schedule.

ADVERSE REACTIONS:
The patient should be informed that the following problems may occur:
- Blurred vision, rainbow, or halos around objects.
- Sensitivity to light (photophobia)
- Dry eyes

When any of the above problems occur, a serious condition such as an infection of the ulcer, neovascularization, or iris 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 events may be due to progressions of the original disease or injury, or they may be due to the effects of wearing a contact lens.

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Disease of injury-related problems:
The eyecare practitioner should discuss with the patient the possibility that the patient's eye 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 the eyecare practitioner IMMEDIATELY if there is an increase in pain or redness, or if the condition gets worse.

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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
Scottsdale, 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 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 upon the eye care 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 lenses 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 Weavers 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, and dry (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.

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 reininsertion 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) DISINFECT:
Clean the 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 wear. 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.

PRECAUTION: 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 ENZYME 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.
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 (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.

LENS CARE TABLE

<table>
<thead>
<tr>
<th>Purpose To: Product Chemical Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
</tr>
<tr>
<td>Rinse</td>
</tr>
<tr>
<td>Disinfect</td>
</tr>
<tr>
<td>Store</td>
</tr>
<tr>
<td>Lubricating &amp; Rewetting</td>
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<tr>
<td>Enzyme</td>
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</tbody>
</table>

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, follow the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.

After removing the lens 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) DISINFECT:
Reheat lenses by filling the lens chambers with the solution which the eyecare practitioner has recommended to keep the lenses wet during disinfection.

AFTER REHEATING, 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.

EMERGENCIES:
The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eye, 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, dioptric power, manufacturing lot number, and expiration date.

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

REPORTING OF ADVERSE 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
Scottsdale, NY 14546
Product Services 1-800-341-2020
www.coopervision.com

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