PACKAGE INSERT for FreshLook® (phemfilcon A) Spherical and Toric Soft Contact Lenses, including: FreshLook® Handling Tint, FreshLook® Colors, FreshLook ColorBlends®, FreshLook Radiance™, and FreshLook Dimensions™ (phemfilcon A) Soft Contact Lenses
When Prescribed for Frequent Replacement or Disposable Wear

096527/D7400C

Important: This package insert is effective as of March 2009 and supersedes all prior inserts for the products described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from CIBA VISION Corporation by calling CIBA VISION Customer Service at 1-800-241-5999 or download from our web-site at www.cibavision.com. CIBA VISION makes available a Patient Instruction Booklet that is recommended to be given to the patient.

Rx only

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

DESCRIPTION

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are available in Handling Tint, Colors, ColorBlends, Radiance and Dimensions. FreshLook Toric soft contact lenses are available in Handling Tint and ColorBlends. The FreshLook soft contact lens family contains several products that incorporate a UV absorber. Each of these products is identified appropriately on the product package. The lens wearing schedule may be prescribed for either Disposable Wear or Frequent Replacement. In the **Disposable Wear Program**, the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Patients should be instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis. In the **Frequent Replacement Program**, the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Each time the lens needs to be removed before the replacement time period has elapsed, the lens must be both cleaned and disinfected prior to placing it back on the eye. CIBA VISION recommends that the lens be discarded and replaced with a new lens every 2 weeks, or as recommended by the eye care professional. The eye care professional is encouraged to determine the wearing schedule based on response of the patient.

PRODUCT DESCRIPTION : Lens Material

The lens material, phemfilcon A, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate and methacrylic acid crosslinked with ethyleneglycol dimethacrylate. FreshLook UV contact lenses contain a proprietary UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light.

FreshLook Colors, FreshLook ColorBlends, and FreshLook Radiance soft contact lenses are made by modifying the clear FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris. FreshLook Dimensions soft contact lenses are made by modifying the tinted FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris. Additionally, a colored pigment is affixed to the front surface of the Toric lens to act as a unique orientation mark identified as (FreshMark). The colored pigments consist of the following color additives listed in the color additive provisions of 21 CFR: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, chromium oxide, carbazole violet, phthalocyanine green, mica coated with iron oxide and mica coated with titanium dioxide.

FreshLook Spherical and Toric with Handling Tint soft contact lenses are tinted green with the color additive phthalocyanine green for easy visibility for handling. FreshLook Dimensions lenses are also tinted green with the color additive phthalocyanine green for a better contrast in the printed portion of the lens. These color additives are not removed by lens handling or cleaning/disinfecting procedures. The lens coloring process does not alter the optical and performance characteristics.

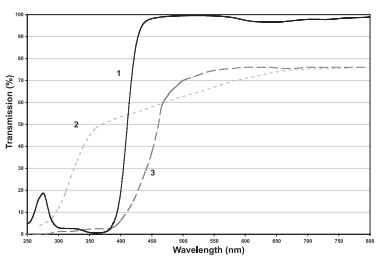
Lens Properties

The physical properties of the lens are:

- Specific Gravity: 1.152
- Refractive Index: 1.409
- Light Transmittance:
  FreshLook with Handling Tint, with or without UV: 95% minimum
  FreshLook Colors with or without UV: 95% minimum
- Surface Character: Hydrophilic
- Water Content: 55%
- Optical Zone: (FreshLook Colors) 5mm
- Optical Zone: (FreshLook with Handling Tint) 5mm to 9mm (varies with power)
- UV Transmittance (for FreshLook UV)†: 0-10% in the ultraviolet portion of the spectrum (250-400nm), averaged across the spectrum.
- Oxygen Permeability (Dk):
  $Dk = 16.1 \times 10^{-11}$ (cm^2 / s) (ml O_2 / [ml · mmHg]) at 35 °C
  (Dr. Irving Fatt Method)
- Oxygen Transmissibility (Dk/L)*:
  $Dk/L = 20 \times 10^{-9}$ (cm / s) (ml O_2 / [ml · mmHg]) at 35 °C
  (Dr. Irving Fatt Method)

†The referenced data was determined from "Methods for Determining Ultraviolet Transmission of UV-blocking Contact Lenses," by Dr. H. Faubl, International Contact Lens Clinic, Vol. 25, no. 5, 1998.
*Representative of the thinnest lens design.
Figure 1 (below) illustrates the transmittance of a typical FreshLook UV with Handling Tint lens (thinnest lens to be marketed), a human cornea and a human lens.
Curve 1 represents the transmittance of the thinnest (0.08mm nominal center thickness) lens to be marketed.

FIGURE 1 : TYPICAL TRANSMITTANCE PROFILE OF A FRESHLOOK UV WITH HANDLING TINT CONTACT LENS VS. A HUMAN CORNEA AND A HUMAN LENS



A small transmittance peak appears in Curve 1 in the 250-290 range. The transmittance across this waveband is 0.12% average, with a maximum of 29%. This peak is located in the wavelength of ultraviolet radiation (250-290nm), which is not transmitted to the earth's surface.
Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24-year-old person and a human lens from a 25-year-old person, respectively.

1. Human cornea from a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillian, 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.

ACTIONS

When placed on the cornea, a hydrated FreshLook Spherical soft contact lens acts as a refracting medium to focus light rays on the retina. The FreshLook Toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina. The thinnest FreshLook UV lenses (-3.50 diopters and lower) block 98% UVA radiation and 94% UVB radiation averaged across the spectrum. The degree of UV radiation blockage of FreshLook UV lenses will increase for thicker lenses. FreshLook Spherical and Toric soft contact lenses with Handling Tint provide ease of patient handling and easy visibility but do not affect iris color. The visibility tint allows the lens to become visible to wearers when not on the eye.

Patients should be advised of the following:
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.

Approved Lens Parameters*

FreshLook soft contact lenses are hemispherical shells of the following dimensions:

Spherical Lens Parameters:

Chord Diameter:	12.0 to 15.0 mm
Center Thickness:	0.08 to 0.56 mm (varies with power) for Daily Wear 0.08 to 0.19 mm (varies with power) for Extended Wear
Base Curves:	7.80 to 9.00 mm
Powers:	-20.00 D to +20.00 D for Daily Wear -20.00 D to +4.50 D for Extended Wear

Toric Lens Parameters:

Chord Diameter:	12.0 to 15.0 mm
Center Thickness:	0.08 to 0.56 mm (varies with power) for Daily Wear 0.08 to 0.19 mm (varies with power) for Extended Wear
Base Curve:	7.80 to 9.00 mm
Powers:	-20.00 D to +20.00 D for Daily Wear -20.00 D to +4.50 D for Extended Wear
Cylinder:	-0.75 D to -6.00 D
Prism Ballasted:	0.25 D
Axis:	0° to 180° in 1° steps

*Parameter availability may vary. Please contact CIBA VISION customer service for currently available parameters.

INDICATIONS (USES)

Vision Correction:

Spherical
FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity. The FreshLook Spherical Colors, ColorBlends, Radiance and Dimensions lenses act to enhance or alter the apparent color of the eye.

Toric
FreshLook Toric (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6.0 diopters. The FreshLook Toric ColorBlends lenses act to enhance or alter the apparent color of the eye.

The lenses may be prescribed for Daily Wear or Extended Wear in not–aphakic persons from 1 to 7 days between removal for cleaning and disinfection or disposal, as recommended by the eye care professional or for Daily Wear in aphakic persons. The eye care professional may prescribe the lens in either the single-use disposable wear or for frequent replacement with cleaning, disinfection and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system. FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

FreshLook soft contact lenses are contraindicated when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Active disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Microbial infection.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity, if not-aphakic).
- Use of medication that is contraindicated, including eye medications.
- Patient history of recurring eye or eyelid infections including styes, or of adverse effects associated with contact lens wear, or of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule or follow-up visit schedule.
- Patient's inability or unwillingness because of age, infirmity or other mental or physical conditions or an adverse working or living environment, to understand or comply with any lens care requirements, warnings, precautions, restrictions or directions.
- Allergy to any ingredient such as mercury or Thimerosal in a solution which must be used to care for the lens.
- Patients who require only vision correction and who would not, or could not, adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- If eyes become red or irritated.
- Any active corneal infection (bacterial, fungal, or viral). Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. Therefore, after a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing professional of all the risks associated with contact lens wear. To minimize these risks, the need for strict compliance with the care regimen including cleaning of the lens case if the patient is on the Frequent Replacement Program, wearing restrictions, wearing schedules, and follow-up visit schedule must be emphasized to the patient (see considerations listed in CONTRAINDICATIONS and PRECAUTIONS Sections).

Since eye injury can develop rapidly, it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care professional or a corneal specialist immediately if they experience any symptoms such as those listed below under the ADVERSE EFFECTS Section. (Professionals examining patients presenting such symptoms should refer to the Professional Fitting Guide and Patient Instruction Booklet).

Extended Wear: The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient; contamination of lens, and/or lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis in contact lens users. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and endothelial polymegethism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of lens wear. The reversibility of endothelial effects of contact lens wear has not yet been established. As a result, professionals' views of extended wearing times vary: some do not prescribe extended wear at all, others prescribe flexible wearing times with occasional overnight wear, and others prescribe extended wearing periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow-up visits, as in the case of the Frequent Replacement Program, with a proper care regimen. Some professionals also recommend frequent replacement of lenses at intervals such as one to two weeks.

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regiment including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.
- Eye problems including corneal ulcers can develop rapidly and if left untreated, lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care professional if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.
- Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.
- Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.
- Smoking increases the risk of corneal ulcers for contact lens users especially when lenses are worn overnight or while sleeping.

PRECAUTIONS

In prescribing contact lenses, the Precautions should be carefully observed. It is also strongly recommended that the professional review with the patient the appropriate Patient Instruction Booklet (describing either the Frequent Replacement Program or the Disposable Wear Program) available from CIBA VISION prior to dispensing the lenses and ensure that the patient understands it contents.

- Due to the small number of patients enrolled in clinical investigation of lenses, not all refractive powers, design configurations, or lens parameters available in the lens material are 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 the eye should be carefully monitored by the prescribing eye care professional.
- In the Disposable Wear Program, the FreshLook soft contact lenses are intended to be disposed of once they are removed from the patient's eye. Therefore, it is important that patients be instructed to always have available a pair of new sterile lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry), the lens should be removed and replaced with a new sterile replacement lens. If replacement lenses are not available, the patient should follow emergency lens care directions.
- In the Frequent Replacement Program, in the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry), the lens should be removed, cleaned and disinfected before reinsertion. If the lens becomes dehydrated, the patient should follow the lens care directions for CARE FOR A DEHYDRATED LENS. In the Frequent Replacement Program, or in the event of Emergency Lens Care in the Disposable Wear Program, chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection.
- In the Frequent Replacement Program or in the event of Emergency Lens Care, CIBA VISION recommends use of sterile solutions. Sterile, non-preserved solutions should be used if the patient is allergic to preservatives; such solutions must be discarded after the time specified in their label directions.
- Contact lens wear may not be suitable for certain occupations or, in other instances, may require eye protection equipment. Therefore, the patient should always inform his/her employer that contact lenses are being worn. Environmental fumes, smoke, dust, vapors, and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea.
- Eye injury from irritation or infection and damage to lenses may result from lens contamination. The patient should be instructed to refrain from using saliva or anything other than the recommended solution for lubricating or wetting lenses. The patient should also be informed to wash and rinse hands before handling contact lenses at all times.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.
- The patient should be informed that contact lenses should not come into contact with any cosmetics, lotions, soaps, creams, hairsprays or deodorants, that it is best to put on lenses before putting on makeup, and that water-based cosmetics are less likely to damage lenses than oil-based products.
- The patient should be informed not to use aerosol or pump products, such as hairspray, while the lenses are worn since liquid and vapors may damage the lens.
- The patient should be instructed to handle the lenses carefully and avoid dropping or touching them with fingernails, which can cause contamination or damage of the lens. The patient should also be told that if the lens becomes nicked or torn, it should not be worn.
- Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand. Lenses should be cleaned in the palm of the hand rather then between thumb and finger.
- Patients should be instructed on and be able to demonstrate prompt removal of the lenses.
- Fluorescein should not be used while the lenses are on the patient's eye. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use and a new lens should be reinserted only after at least one hour.
- A lens must move freely on the eye for a proper fit. For further information, refer to the appropriate FreshLook soft contact lens Professional Fitting Guide.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing and professionals should conduct early and frequent follow-up examinations to determine ocular response to extended wear.
- To prevent contamination and avoid serious eye injury, the patient should be instructed to empty and rinse the lens case with fresh rinsing solution and allow the lens case to air dry between each lens disinfection cycle as in the Frequent Replacement Program, or in the event of Emergency Lens Care.
- The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care professional before using any medication in the eye.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Should these conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- A patient who has been prescribed FreshLook contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping.

ADVERSE EFFECTS:

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Foreign body sensation
- Excessive watering (tearing) of the eyes or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when lens was first placed on eye
- Poor visual acuity
- Blurred vision, rainbows, or halos around objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms, he or she should be instructed to **IMMEDIATELY REMOVE THE LENSES.**

- If the discomfort or problem stops, look closely at the lens.
  - If the lens is in any way damaged, DO NOT put the lens back in the eye. Discard the lens.
  - If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops, clean, disinfect and reinsert the lens if in the Frequent Replacement Program or discard the lens and replace it with a new sterile replacement lens if in the Disposable Wear Program.
- If the discomfort or problem continues after removal of the lens or upon reinsertion, immediately remove lenses and promptly contact his or her eye care professional. The eye care professional must determine the need for examination, treatment or referral without delay.
- Patients should be informed that a serious condition such as infection, corneal ulcer, corneal vascularization or iritis may be present and may progress rapidly. Less serious reactions, such as abrasions, epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications. Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrations, neovascularization, endothelial polymegethism, tarsal papillary changes, conjunctival infection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of FreshLook (phemfilcon A) contact lenses, eye care professionals please notify CIBA VISION Corporation technical consultation at 1-800-241-7468.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

- The lens must move adequately on the eye for a proper fit and continued health of the eye. When prescribing FreshLook lenses for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.
- Conventional methods of fitting contact lenses apply to FreshLook soft contact lenses. For a detailed description of the fitting technique, refer to the appropriate CIBA VISION *Professional Fitting Guide.*
- It is strongly recommended that the patient be provided appropriate *Patient Information Booklet* available from CIBA VISION and understands its contents prior to dispensing the lenses.
- Copies of **Fitting Guides** and **Patient Information Booklets** for FreshLook lenses are available without charge from: CIBA VISION Corporation, Duluth, Georgia USA 30097 or by calling a CIBA VISION customer service representative at 1-800-241-5999.

LENS REPLACEMENT SCHEDULES

In a **planned replacement program**, the replacement schedule is determined by the eye care professional based upon the patient's physiological condition. CIBA VISION recommends frequent replacement of FreshLook lenses at intervals of every two weeks. The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary. When FreshLook lenses are prescribed for **disposable wear** the contact lens is considered a single use medical device in which the lenses are worn from 1 to 7 days and **discarded upon removal** from the eye.

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. CIBA VISION recommends that contact lens wearers see their eye care professional twice each year or, if directed, more frequently. The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. The eye care professional may prescribe the lens for frequent replacement with cleaning, disinfection and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical (not heat) disinfection system.

DAILY WEAR: There may be a tendency for the daily wear patient to over-wear the lenses initially. Therefore, the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional and provided to the patient. These lenses may be worn in the Frequent Replacement Program.

EXTENDED WEAR: (Greater than 24 hours or while asleep) The wearing schedule should be determined by the prescribing eye care professional for each individual patient, based upon a full examination and patient history as well as the professional's experience and professional judgment.

CIBA VISION recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The eye care professional should examine the patient in the early stages of extended wear in order to determine corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care professional. (See the factors discussed in WARNING Section). Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care professional.

LENS CARE DIRECTIONS

Disposable Wear (Emergency Lens Care):

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available. (See BASIC INSTRUCTIONS FOR LENS CLEANING AND DISINFECTION below.)

Planned Replacement:

- Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional.
- Failure to follow the complete regimen in accordance with the manufacturer's package inserts and patient instructions may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the patient must be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system. The specific instructions for such products and the particular characteristics of the patient should also be taken into consideration.

The basic general instructions for general lens care are as provided below:

- Always wash and rinse your hands before handling your contact lenses.
- The lenses should be cleaned and disinfected before reinsertion into the eye. Use a suggested chemical (not heat) lens care system recommended by the professional since heat may cause discoloration.
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses.
- Always use lens care solutions before they reach the expiration date.
- Always keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored).
- In the Frequent Replacement Program, CIBA VISION recommends that sterile solutions be used in the soft lens care system. Sterile non-preserved solutions should be used only if the patient is allergic to preservatives. When used, sterile non-preserved solutions must be discarded after the time specified in their label directions.

Refer to the PRECAUTION Section for further information on lens care and handling.

CARE FOR A DEHYDRATED LENS

Disposable Wear Program: If a soft (hydrophilic) contact lens is exposed to air while off the eye, it may become dry and brittle. Dehydrated lenses should be disposed of. Therefore, it is important that the patient always have a pair of new sterile replacement lenses available.

Frequent Wear Program: If a soft (hydrophilic) contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply sterile saline solution before handling.

Eye care professionals should review the following information on rehydrating the lens with the patient:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If, after soaking, the lens does not become soft, the lens should not be used until examined by the eye care professional.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, the patient should be instructed to apply several 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 several minutes, the patient should be instructed to immediately consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a sealed blister pack containing borate buffered saline. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

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 call or visit the eye care professional or a hospital emergency room without delay**.

HOW SUPPLIED

Each sterile lens is packaged in a foil-sealed plastic container containing a borate buffered saline solution with 0.005% poloxamer and is steam sterilized. The package is marked with the lens power, diameter, base curve, cylinder and axis (if applicable), expiration date, manufacturing lot number and, if applicable, UV-absorber, lens tint and opaque color.

ADDITIONAL INFORMATION

For answers to your questions about FreshLook soft contact lenses or to report any adverse reactions, contact our Professional Consultation Services at 1-800-241-7468 during regular business hours.
For additional copies of the Eye Care Professional Package Insert, Professional Fitting Guide and Patient Instruction Booklets, contact our Customer Service Department at 1-800-241-5999.

PATENT PROTECTED

U.S. Patents: 5,020,898; 5,936,705; 5,414,477; 5,637,726; 6,494,575;
GB Patents: 0498835; 0440107
FR Patents: 0498835; 0440107
AUS Patent: 636679
CN Patent: 26003
PH Patent: 29984
SG Patent: 9790791-9
TW Patent: NI-63667

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CIBA VISION