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 FreshLook Handling Tint, FreshLook COLORS, FreshLook COLORBLENDS, and FreshLook Toric. FreshLook soft toric contact lenses are available in FreshLook Handling Tint and FreshLook 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. As a Frequent Replacement lens, the lens wearing time prescribed by the eye care professional is for daily wear. 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 your eye care professional.

PRODUCT DESCRIPTION: Lens Material

The lens material, phemfilcon A, is a hydrophilic copolymer of 2-hydroxyethyl metacrylate and 2-ethylhydroxyethyl metacrylate and contains epoxy methacrylate and ethylene glycol 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 and FreshLook COLORBLENDS 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. Additionally, a colored pigment is affixed to the front surface of the Toric lens to act as a unique orientation mark identified as (PTU). The colored pigments consist of the following color additives listed in the color additive provisions of 21 CFR: iron oxides, titanium dioxide, [thiophene-2-carboxaldehyde (2-)] copper, chromium oxide, barium sulfate, polyvinyl alcohol, mica coated with iron oxides and mica coated with titanium dioxide.

Oxygen Permeability (Dk) and Oxygen Transmissibility (Dk/L)**:

- Dk = 16.1x10^{-11} (cm² / s) (ml O₂ / [ml · mmHg]) at 35 °C
- Dk/L = 3.50 diopters and lower: block 98% UVA radiation and 94% UVB radiation averaged across the spectrum. This is less than the UVA and UVB radiation blockage of FreshLook UV lenses will increase for thicker lenses. FreshLook Handling Tint, Spherical and Toric soft contact lenses 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 cornea.

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. This is less than the UVA and UVB radiation blockage of FreshLook UV lenses.

Toric Lens Parameters:

- Center Diameter: 12.0 to 15.0 mm
- Center Thickness: 0.00 to 0.09 mm (varies with power)
- Base Curve: 7.80 to 9.00 mm
- Topographer: -20.00 D to +20.00 D
- Cylinder: -0.50 D to +1.50 D
- Prism Ballast: 0.25 D
- Axis: -100° to +100° in 1° steps

Approved Lens Parameters†

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

- Chord Diameter: 14.5 mm
- Center Thickness: 0.00 to 0.09 mm (varies with power)
- Base Curve: 7.80 to 9.00 mm
- Spherical Power: -20.00 D to +20.00 D
- Cylinder: -0.50 D to +1.50 D
- Prism Ballast: 0.25 D
- Axis: -100° to +100° in 1° steps

The referenced data was determined from “Methods for Determining Ultraviolet Transmission of UV-Blocking Contact Lenses,” by Dr. H. Fatt, International Contact Lens Clinic, Vol. 25, no. 5, 1998.

INDICATIONS (USES) Vision Correction: Spherical

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for daily wear 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* COLORS, FreshLook* COLORBLENDS*, and FreshLook* 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 daily wear 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 4.0 diopters. The FreshLook COLORBLENDS Toric lenses act to enhance or alter the apparent color of the eye.

The eye care professional may prescribe the lens for frequent replacement with daily removal for cleaning and disinfection. 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 TO NOT USE)

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

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abrasivity affecting the cornea, conjunctiva or eyelids
- Microbial infection
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal neurotaxis (reduced corneal sensitivity, if not anaphylactic)

Usage of medication is contraindicated, including eye medications.

- History of recurring eye or eyelid infections including sties, or of adverse effects associated with contact lens wear, or of sensory or abnormal ocular contact response to contact lens wear.

- History of patient non-compliance with contact lens care and disinfection, wearing regulations, restrictions, wearing schedule or follow-up visit schedule.

- Patient 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 warnings, precautions or restrictions.

- Allergy to any ingredient such as mercurial or tinyl in a solution.

- Patients 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 contact lens wear.

- If eyes become red or irritated.

Serious eye injury and loss of vision may result from problems associated with wearing contact lens products and using contact lens care products. Therefore, after a thorough eye examination, including any required appropriate diagnostic tests, the prescribing professional of all the risks associated with contact lens wear should inform the patient about the contact lens care regimen including cleaning of the lens, wear restrictions, wearing schedules and follow-up visit schedule must be emphasized to the patient. (See PRECAUTIONS Sections).

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Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and proper precautions, and provide their eye care professional if they should experience eye discomfort, foreign body sensation, excessive tearing in the presence of conditions, redness of the eye or other problems with their eyes.

Non-compliance with the manufacturer's labeled care regimen 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 smoking while sleeping. Studies have shown that contact lens wearers who smoke have a higher incidence of corneal ulcerative keratitis than those who are non-smokers.

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 available from CIBA VISION to discontinue/discontinue and ensure that the patient understands its contents.

Due to the 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. When selecting an appropriate lens design and parameters, the eye care professional should consider characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thicknesses, 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 corrective 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 event that a lens must be removed from the eye because of dust, a foreign body, friction, or contamination on the lens or the lens becomes dehydrated (dry), the lens should be removed, cleaned and rehydrated if appropriate. The dehydrated, the patient should follow the lens care directions for CARE FOR A DEHYDRATED LENS. Chemical disinfection solution may be used. If the condition is sustained, specific indications for lens care, see ADVERSE EFFECTS.

- 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 under label.

- Contact lens wear may not be suitable for certain occupations or, in other instances, may require eye protection equipment. Therefore, the patient should inform his employer that contact lenses are being worn. Environmental fumes, smoke, and dust must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea.

- Eye irritation or inflammation and damage to lenses may result from lens contamination. The patient should be instructed to refrain from handling contact lenses 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.

- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

- The patient should be informed that contact lenses should not come into contact with any cosmetics, lotions, soaps, creams, hairsparys 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 hairspary, while the lenses are worn since liquid can be aspirated into the eye. The patient should be instructed to handle the lenses carefully and avoid dropping or touching them with fingernails, which can cause scratches, abrasions, epithelial staining and ruptures. 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 hands. Lenses should be cleaned in the palm of the hand rather than 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. Due to the sensitivity of the eye and the potential for damage to the eye, a fluorescein trial should be done before the patient begins wearing the contact lenses.

- The patient should be instructed to empty and rinse the lens case with fresh rinsing solution and allow the lens case to dry to air dry between lens cleaning cycles.

- 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, bathing, 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 lens tolerance when using contact lenses. Patients should be cautioned to use the prescribed lenses.

- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause drying of the eye, increased lens awareness or blurred vision. Should these conditions exist, proper moisture conditions of the lenses should be maintained.

- Do not share your lenses with anyone as this may spread the infection. CIBA VISION recommends that contact lenses be used by one patient at a time.

- 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 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 should then refer them for examination, treatment or referral without delay.

ADVERSE EFFECTS

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

- Foreign body sensation
- Excessive watering (tearing) of the eyes or other eye secretions
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging, itching or other pain associated with the eyes
- Video visual loss or blurring
- Blurred vision, rainbows, or halos around objects
- Feeling of dryness

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

- If the discomfort or problem persists, or 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, wash, rinse, and discard the lens.

- 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 should then refer them for examination, treatment or referral without delay.

- Patients should be informed that a serious condition such as infection, corneal ulcer, corneal vasularization or iritis may be present and may progress rapidly. Less serious reactions, such as conjunctivitis, epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications.

- Additional adverse reactions 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, interstitial, neovascularization, endothelial polymegathy, tarsal papillary changes, conjunctival infection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse events associated with the use of FreshLook* (phemfilcon A) contact lenses, please notify CIBA VISION customer service representative at 1-800-241-5999.

FITTING GUIDES AND PATIENT INSTRUCTION BOOKS

- The lenses must be made accurately on the eye for a proper fit and continued health of the eye.

- Conventional Frente of fitting contact lenses apply to FreshLook soft contact lenses. For a detailed description of the fitting techniques, 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 lenses.

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 ensure 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 re-used by the patient 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

- Gentle sterile is packaged in a foil-sealed plastic container containing a borate buffered saline solution with 0.005% povidone and is steam sterilized. The package is marked with the lens power, date, batch code, example of two letter code language (English) and a 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.

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CIBA VISION
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