

IMPORTANT: This package insert is effective as of 12/2005 and supersedes all prior inserts for the product 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. Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service in the US at 1-800-241-5999 or download a copy from our website at www.cibavision.com. The eye care professional should provide patients appropriate instructions that pertain to the patient's prescribed lenses. CIBA Vision makes available a Patient Instruction Booklet which is recommended to be given to patients.



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

PRODUCT DESCRIPTION

FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are available in a spherical lens design. The lenses are to be prescribed for single use daily disposable wear. The lens material is approx. 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are printed with an intermittent coating containing a combination of the following pigments: iron oxides, titanium dioxide, [phtalocyaninato (2-)] copper, chromium oxide and carbazole violet.

LENS PROPERTIES

- Specific gravity: 1.06
- Refractive index: 1.38 (hydrated)
- Light transmittance: Clear ≥ 97%
- Oxygen permeability: (Dk): 26×10^{-11} (cm²/sec) (ml O₂/ml x mm Hg) at 35°C (Fatt corrected)
- Water content: approx. 69% by weight in normal saline

LENS PARAMETERS¹

FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available: Plano and -0.50D to -6.00D (0.25D steps)
- Center thickness: 0.10 at -3.00D; 0.15 at +3.00D (varies with power)
- Optic zone diameter: 7.6 to 8.0 mm (varies with power)

ACTIONS

When hydrated and placed on the cornea FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS

FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia, hyperopia) in non-aphakic persons with non-diseased eyes. The FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses also act to enhance or alter the apparent color of the eye.

The FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are to be prescribed for single-use Daily Disposable Wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single-use.

CONTRAINDICATIONS

DO NOT USE FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids that may be exaggerated by contact lens wear.
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may be exacerbated by or interferes with contact lens wear.
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated by the wearing of contact lenses.
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as thimerosal) to which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal or viral).
- The use of any medication that is contraindicated or interferes with contact lens wear, including eye medications.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- If eyes become red or irritated.

WARNINGS

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

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of their lenses. **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear their lenses while sleeping. Clinical study results² have shown that the risk of ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Studies have also shown that contact lens wearers who smoke have an estimated 3 to 8 times greater risk of suffering ulcerative keratitis than among those who are nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems they should be instructed to immediately remove their lenses and promptly contact their eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

Special Precautions to the Eye Care Professional:

Due to small numbers of patients enrolled in the clinical investigation 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 eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, 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.

- 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, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continuing health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. CIBA Vision recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye care professionals should carefully instruct patients about the following safety precautions:

- Carefully follow the handling, insertion, removal, and wearing instructions in the FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lens Professional Fitting and Information Guide and any additional instructions provided by the eye care professional.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep spare lenses available to avoid reusing the lenses.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash and rinse hands before handling lenses.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand.
- Never use tweezers or other sharp objects such as fingernails to remove the lens from the container to avoid damaging the lens.

- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface which can irritate the eye. Replace with a sterile fresh, new lens.
- Consult the eye care professional about wearing lenses during sporting and water related activities. 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.
- Avoid all harmful or irritating vapors or fumes while wearing lenses.
- Promptly remove a lens to avoid serious injury in the event that dust, a foreign body or other contaminant gets between the lens and the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile fresh, new lens.
- Patients should be instructed to remove their lenses before sleeping.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the section Care for a Sticking Lens. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- Patients should inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or restrict the use of contact lenses in certain work environments.
- Patients should inform their physician that contact lenses are worn and should consult their eye care professional before using any medication in the eye.
- Do not use lenses beyond the expiration date.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. Patients should be informed of these potential conditions and proper remedial treatment should be prescribed if any of these conditions occur. Depending on the severity of the condition appropriate treatment may include the use of rewetting drops intended for use with soft contact lenses or temporary cessation of contact lens wear until the condition subsides.

It is strongly recommended that patients be provided with a copy of the FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lens Professional Fitting and Information Guide available from CIBA Vision and understand its contents prior to dispensing the lenses.

ADVERSE REACTIONS

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

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

If any of the previous signs or symptoms occur:

- The patient should **IMMEDIATELY REMOVE THE LENS(ES)**. If the discomfort or problem stops, the patient should discard the lens and replace it with a new one. **IF THE PROBLEM CONTINUES AFTER INSERTING A NEW LENS, THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENS(ES) AND CONTACT THEIR EYE CARE PROFESSIONAL AT ONCE.**
- Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegethism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE REACTION REPORTING

If a patient experiences any serious adverse effects associated with the use of FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses, licensed eye care professional please notify: CIBA Vision Corporation Technical Consultation at 1-800-241-7468.

FITTING

For a detailed description of the fitting techniques, refer to the FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses Professional Fitting and Information Guide, copies of which are available free of charge from: CIBA Vision Corporation (1-800-241-5999) 11460 Johns Creek Parkway, Duluth, GA. 30097 U.S.A.

REPLACEMENT AND WEAR SCHEDULE

FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

WEARING SCHEDULE

• DAILY WEAR (Less than 24 hrs. while awake)

- The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to over-wear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have **not** been conducted to show that FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

SEASONAL OCULAR ALLERGY WEARERS

A one-month subjective trial of contact lens wearers with a history of seasonal allergic conjunctivitis was conducted during a month of expected high pollen count in various US cities. Information was collected about allergy-related symptoms, wear-time and comfort during lens wear.

Study results found that these contact lens wearers experienced fewer days of burning and redness when wearing (nelfilcon A) based contact lenses as compared to a new pair of their usual lenses. The effects of allergy medications that may have been used during the study were not assessed.

EMERGENCY LENS CARE

Cleaning and disinfection of the lens is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

CARE FOR A STICKING OR TORN LENS

If a lens sticks (stops moving) or cannot be removed from the eye, instruct the patient to apply 1 to 2 drops of a recommended lubricating or rewetting solution in accordance with package labeling. The patient should blink forcefully several times, then while looking up slide the lens down onto the white part of the eye and remove the lens by pinching it between the thumb and forefinger. If the lens continues to stick, the patient should immediately consult the eye care professional.

If a lens tears in the eye it will feel uncomfortable. Advise patients it is not possible to lose a contact lens or part of a contact lens behind the eye and that they should calmly remove the pieces by carefully pinching them as they would for normal lens removal. If lens pieces do not seem to remove easily the eye may be rinsed with sterile saline. Excessive pinching should be avoided. If rinsing with saline does not help, instruct patients to contact the eye care professional for assistance. Lenses can be easily located by the eye care professional using fluorescein.

GENERAL EMERGENCIES

Patients 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 OR FRESH SALINE SOLUTION, REMOVE AND DISCARD THE LENS, AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

Additional information regarding emergency treatment may be provided on the product container label.

HOW SUPPLIED

FreshLook® ONE-DAY (nelfilcon A) Color Soft Contact Lenses are packaged in strips of five foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution and are steam sterilized. Five blister pack containers are attached to form a single strip. The package storage saline may also contain up to 0.02% Poloxamer 108. The base curve, lens power, lot number and expiration date are marked on the foil seal of each individual container. The diameter is marked on the rightmost container of each strip of five blister packs.

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¹Check for actual product availability as additional parameters may be introduced over time.

²New England Journal of Medicine, September 21, 1989; 321 (12) pp. 773-783.

