Oxygen permeability (Dk): 26 x 10^-11

Soft (hydrophilic) One-Day Contact Lenses are available in a toric design.

FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) (hydrophilic) One-Day Contact Lenses are available in a spherical lens design.

FOCUS® DAILIES® and DAILIES® AquaComfort Plus® (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in a toric design.

FOCUS® DAILIES® Progressives and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) Soft (hydrophilic) One-Day Contact Lenses are available in a multifocal lens design. The lenses are designed to be prescribed for single use, daily disposable wear.

LEN S MATERIAL

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol acrylamide copolymer).

• For VISITINT® lenses, the color additive cobalt phthalocyanine is added to the lens material to create a light blue edge to edge color to make them easier to see when handling.

• Print marks on FOCUS® DAILIES® Toric and DAILIES® AquaComfort Plus® Toric (nelfilcon A) contact lenses contain the color additive phthalocyanine blue as a coded pattern.

LENS PROPERTIES

FOCUS® DAILIES® (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available:
  - -6.00 D to -6.00 D (0.25 D steps)
  - -5.00 D to -10.00 D (0.50 D steps)
  - -4.00 D to -6.00 D (0.50 D steps)
- Center thickness:
  - 0.10 mm at -3.00 D
  - 0.10 mm at -6.00 D (varies with power)
- Tint:
  - Light blue handling tint

FOCUS® DAILIES® Toric (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 14.2 mm
- Powers available:
  - -6.00 D to -6.00 D (0.25 D steps)
- Center thickness:
  - 0.10 mm at -3.00 D
  - 0.10 mm at -6.00 D (varies with power)
- Tint:
  - Light blue handling tint

FOCUS® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 13.8 mm
- Powers available:
  - -5.00 D to -6.00 D (0.25 D steps)
  - -4.00 D to -6.00 D (0.25 D steps)
  - -3.00 D to -6.00 D (0.25 D steps)
  - -2.00 D to -6.00 D (0.25 D steps)
- Center thickness:
  - 0.11 mm at -3.00 D
  - 0.10 mm at -6.00 D (varies with power)
- Tint:
  - Light blue handling tint

DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.7 mm
- Diameter: 14.4 mm
- Powers available:
  - -4.00 D to -6.00 D (0.25 D steps)
  - -3.00 D to -6.00 D (0.25 D steps)
  - -2.00 D to -6.00 D (0.25 D steps)
  - -1.00 D to -6.00 D (0.25 D steps)
  - -0.50 D to -6.00 D (0.25 D steps)
- Center thickness:
  - 0.10 mm at -3.00 D
  - 0.10 mm at -6.00 D (varies with power)
- Tint:
  - Light blue handling tint

DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses are available in the following dimensions:

- Base curve: 8.6 mm
- Diameter: 14.6 mm
- Powers available:
  - -6.00 D to -6.00 D (0.25 D steps)
  - -5.00 D to -10.00 D (0.50 D steps)
  - -4.00 D to -6.00 D (0.25 D steps)
  - -3.50 D to -6.00 D (0.25 D steps)
  - -3.00 D to -6.00 D (0.25 D steps)
  - -2.00 D to -6.00 D (0.25 D steps)
  - -1.00 D to -6.00 D (0.25 D steps)
  - -0.50 D to -6.00 D (0.25 D steps)
- Center thickness:
  - 0.10 mm at -3.00 D
  - 0.10 mm at -6.00 D (varies with power)
- Tint:
  - Light blue handling tint

LENS DESCRIPTION

THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

The lenses are available in the following powers and base curve:

- Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.25 D, -2.75 D, -3.00 D, -3.25 D, -3.75 D, -4.00 D, -4.50 D, -5.00 D, -5.75 D, -6.00 D, -6.50 D, -7.00 D, -7.50 D, -8.00 D (0.50 D steps);

- Axis: 20°, 70°, 90°, 110°, 160°, 180°;

- Base curve: 8.6 mm (variability with power);

- Diameter: 13.8 mm (varies with power);

- Tint: Light blue handling tint

Effective Range up to +3.00 D

- Powers available: +6.00 D to -10.00 D (0.25 D steps);

- Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.00 D, -2.50 D, -3.00 D, -3.50 D, -4.00 D, -4.50 D, -5.00 D, -5.75 D, -6.00 D, -6.50 D, -7.00 D, -7.50 D, -8.00 D (0.50 D steps);

- Axis: 20°, 70°, 90°, 110°, 160°, 180°;

- Base curve: 8.6 mm (variability with power);

- Diameter: 13.8 mm (varies with power);

- Tint: Light blue handling tint

Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all the characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, central and peripheral thickness, and optical design.

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 continuous 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 do not fluoresce. However, 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 direct saline from the eye care professional’s hands.

Patients who wear contact lenses to correct myopia may not achieve the best corrected visual acuity for either far or near vision. Visual retraining of these patients is recommended.

Eye Care Professionals should carefully instruct patients about the following safety precautions:

- Carefully follow the handling, insertion, removal, and wearing instructions in the DAILIES® (nelfilcon A) One-Day Contact Lenses Patient Instruction Booklet 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 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 contact lenses are not cleaned or disinfected and should be discarded after a single use.

- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.

- 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, surfing, or water sports 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.

- 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 conditions subsides.

- It is strongly recommended that patients be provided with a copy of the DAILIES® (nelfilcon A) One-Day Contact Lenses Patient Instruction Booklet available from Alcon Laboratories and understand its content prior to dispensing the lenses.
ADVERSE REACTIONS
Potentially serious complications are usually accompanied by one or more of the following signs or 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 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 persists, 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 LENSES AND CONTACT AN 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, irritations 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 polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE REACTION REPORTING
If a patient experiences any serious adverse effects associated with the use of DAILIES® (nelfilcon A) One-Day Contact Lenses, licensed eye care professionals please notify: Alcon Medical Safety in the USA at 1-800-241-7468.

FITTING
For a detailed description of the fitting techniques, refer to the DAILIES® (nelfilcon A) One-Day Contact Lenses Professional Fitting and Information Guide, copies of which are available free of charge from: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134
1-800-241-5999

REPLACEMENT AND WEAR SCHEDULE
DAILIES® (nelfilcon A) One-Day 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 hours, white 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. There may be a tendency for patients to overwear 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 DAILIES® (nelfilcon A) One-Day 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.

CLINICAL DETAILS

- Seasonal 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 FOCUS® DAILIES® 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.

- All Day Comfort

  A one month study of 188 subjects was conducted for the purpose of evaluating comfort and wearing time for FOCUS® DAILIES® soft contact lenses. End of day comfort was measured using a 0 to 10 scale where 0 was unacceptable and 10 was excellent. Wearing time was also recorded in hours of wear per day. Baseline values for end of day comfort and average wearing time with the subject’s pre-study lenses were 6.9 out of 10 and 13.5 hours, respectively. Study results found that the average end of day comfort for FOCUS® DAILIES® contact lenses was 7.8 out of 10 with an average wearing time of 14.3 hours. The values for FOCUS® DAILIES® were statistically different compared to the baseline values collected from the pre-study lenses. As in this study, individual results may vary.


- DAILIES® AquaComfort Plus®

  A one-month study was conducted for the purpose of evaluating the performance for FOCUS® DAILIES® AquaComfort Plus® lenses. Subjective performance measures were evaluated by having the subjects rate these attributes on a scale from 1 to 10, where 1 was “poor/not at all satisfied” and 10 was “excellent/completely satisfied.” For both their previous FOCUS® DAILIES® lenses as well as DAILIES® AquaComfort Plus® lenses, Subjects rated DAILIES® AquaComfort Plus® contact lenses statistically better for comfort at insertion compared to their own FOCUS® DAILIES® All Day Comfort lenses. Specifically, average comfort at insertion was 9.0 at baseline with FOCUS® DAILIES® lenses and was 9.5 at one-month with DAILIES® AquaComfort Plus® lenses. Additionally, average overall comfort was 8.8 at baseline with FOCUS® DAILIES® and was 9.1 at one-month with DAILIES® AquaComfort Plus®, while the average comfort at the end of the day was 7.8 at baseline with FOCUS® DAILIES® lenses and was 8.5 at one-month with DAILIES® AquaComfort Plus® lenses (changes not statistically significant).

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 the 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 the manufacturer’s instruction for use 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 the lens tears in your 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 do for normal lens removal. If the lens pieces do not seem to remove easily the eye might 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.

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

DAILIES® (nelfilcon A) One-Day Contact Lenses are packaged in strips of five foil sealed blister packs containing 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 contain up to 0.05% Polysamer. In addition, the package storage saline for DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and ULLEN® AquaComfort Plus® Multifocal One-Day Contact Lenses contains polyethylene glycol (PEG) and hydroxypropyl methylcellulose (HPMC). The package is marked with the base curve, diameter, dioptric power, manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs Description
\[ \text{CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.} \]
\[ \text{Steam sterilized} \]
\[ \text{Use by date (Expiry date)} \]
\[ \text{Example of two letter language code (English)} \]
\[ \text{Do Not Reuse} \]
\[ \text{DiA Diameter} \]
\[ \text{BC Base curve} \]
\[ \text{PWR Lens power} \]
\[ \text{LO “Low” near ADD} \]
\[ \text{MED “Medium” near ADD} \]
\[ \text{HI “High” near ADD} \]
\[ \text{European conformity sign} \]
\[ \text{Authorized Representative European Community} \]
\[ \text{Manufacturer} \]
\[ \text{Packaging waste license sign} \]