

IMPORTANT: This package insert is effective as of March 2016 and applicable to the delefilcon A contact lenses 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 Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition, a Patient Instruction Booklet is available which is recommended to be given to patients.



CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.

PRODUCT DESCRIPTION

DAILIES TOTAL1* and DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue tint, which makes them easier to see when handling.

Lens Properties

- Refractive Index hydrated: 1.42
- Light Transmittance: 93% (@ 610 nm, -1.00D)
- Oxygen Permeability (Dk): 140×10^{-11} (cm²/sec)(ml O₂/ml x mm Hg), measured at 35° C (intrinsic Dk-Coulometric method)
- Water Content: 33% by weight in normal saline
- Surface Water Content: ≥ 80%

Lens Parameters

- Diameter Range: 13.0 to 15.0 mm
- Spherical Power Range: -20.00 to +20.00D
- Base Curve Range: 8.0 to 9.2 mm

Lens Parameters Available¹

DAILIES TOTAL1* (delefilcon A) spherical

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00D (varies with power)
- Base Curve: 8.5 mm
- Powers: -0.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps) +0.50 to +6.00D (0.25D steps)

DAILIES TOTAL1* Multifocal (delefilcon A)

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00D (varies with power)
- Base Curve: 8.5 mm
- Powers: +6.00D to -10.00D (0.25D steps) ADD: LO, MED, HI

NOTE: Hereafter, **DAILIES TOTAL1* spherical lenses** and **DAILIES TOTAL1* Multifocal** contact lenses will simply be referred to as delefilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, **delefilcon A** contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

DAILIES TOTAL1* (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1* Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The 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 (REASONS NOT TO USE)

DO NOT use delefilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye

- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoaesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- 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
- 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

Advise patients 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 directions and all labeling instructions for proper use of lenses and lens care products. **Serious 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 lenses while sleeping. Clinical study results have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight².
- Studies² have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional:

Due to the small number 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's 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.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- 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 continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate

follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.

- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- 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:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, rinse and thoroughly dry hands with a lint-free towel before handling lenses.**
- REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Ensure that the correct lens for each eye is available. 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. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
 - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
 - Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
 - Use the fingers of the other hand to lift the upper eyelid.
 - Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
 - Look down and slowly remove the hand, releasing the lower lid.
 - Look straight ahead and slowly remove the other hand, releasing the upper lid.
 - Blink gently.
- To remove lenses:
 - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. **Make sure hands are clean and completely dry.**
 - Blink fully several times.
 - While looking up, slide the lens down onto the white part of the eye.
 - Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
 - If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- If a lens decenters on the eye, it may be possible to recenter it by:
 - Closing the eye and massaging the lens into place, or
 - Looking in the direction of the lens and blinking gently, or
 - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- 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 **Care for a Sticking Lens** section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.

- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids 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.
- 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.
- 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.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know that the Patient is Wearing Contact Lenses:

- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **DAILIES TOTAL1*** and **DAILIES TOTAL1* Multifocal Contact Lenses** (delefilcon A) Patient Instruction Booklet available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear.

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

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or 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

WHAT TO DO IF A PROBLEM OCCURS

Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops**, discard the lens and replace it with a new one.
- **If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient 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 carefully to avoid more serious 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, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of **DAILIES TOTAL1*** brand (delefilcon A) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to delefilcon A contact lenses. For a detailed description of the fitting techniques, refer to the **DAILIES TOTAL1*** and **DAILIES TOTAL1* Multifocal Contact Lenses** (delefilcon A) Professional Fitting and Information Guide. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES

DAILY WEAR (less than 24 hours, while awake):

- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
 - 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 delefilcon A 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.
- Delefilcon A contact lenses are intended to be worn once (daily disposable wear) 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.

EMERGENCY LENS CARE

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

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should **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 blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and 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 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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized **STERILE**. The package is marked with the base curve, diameter, dioptric power and ADD power (multifocal lenses), manufacturing lot number and expiration date.

The following may appear on the labels or cartons:

Symbols/Signs/Abbreviations	Description
	CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
	Steam sterilized
	Use by date (Expiry date)
	Batch code
	Do not reuse
	Do not use if blister package is damaged
	Example of two letter language code (English)
	Diameter
	Base curve
	Power
	Dioptric (lens power)
	Addition power
	European conformity sign
	Caution
	See product instructions
	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

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Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
www.alcon.com
1-800-241-5999

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

² Schein, OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily Wear and Extended Wear Soft Contact lenses. N Eng J Med. 1989; 323(12):773-783