

INSTRUCTIONS FOR USE - THIS LEAFLET CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION. PLEASE READ CAREFULLY AND RETAIN FOR FUTURE REFERENCE. CONTACT LENSES SHOULD ALWAYS BE FITTED BY AN EYE CARE PROFESSIONAL. IT IS ESSENTIAL THAT YOU FOLLOW YOUR EYE CARE PROFESSIONAL'S DIRECTIONS AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF YOUR CONTACT LENSES.

PRODUCT IDENTIFICATION (Name):

- DAILIES TOTAL1* (delefilcon A) Water Gradient One-Day Soft Contact Lenses
- DAILIES TOTAL1* Multifocal (delefilcon A) Water Gradient One-Day Soft Contact Lenses

PRODUCT DESCRIPTION

DAILIES TOTAL1* (delefilcon A) Water Gradient Contact Lenses are made from a lens material that is approximately 33% water and 67% delefilcon A, a silicone containing hydrogel with added phosphatidylcholine. The color additive copper phthalocyanine is added to the lens material to create a light blue edge-to-edge color to make it easier to see when handling. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water.

Lens Properties:

- Refractive Index hydrated: 1.42
- Light Transmittance: $\geq 93\%$ (@ 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: $\geq 80\%$

INTENDED USE

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 presbyopia, with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (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 used for single use, daily disposable wear (less than 24 hours while awake) only.

CONTRAINDICATIONS (Reasons Not to Use)

Do not use (delefilcon A) contact lenses when any of the following exists:

- Allergy, inflammation, infection or irritation in or around the eye or eyelids
- Inadequate tear film (dry eye)
- Corneal hypoesthesia (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
- If eyes become red or irritated

WARNINGS

- Daily wear lenses are not indicated for overnight wear. Delefilcon A lenses should not be worn while sleeping.
- Serious eye problems, including corneal ulcers (ulcerative keratitis), can develop rapidly and lead to loss of vision.
- Contact lens wear increases the risk of eye infections. Sleeping in lenses and/or smoking further increases the risk of ulcerative keratitis for contact lens users (Schein 1989).
- 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.
- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential to follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products.

General Emergencies:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes:

- Flush eyes immediately with fresh saline solution or tap water.
- Remove and discard the lens and immediately contact your eye care professional or visit a hospital emergency room without delay.

PRECAUTIONS

Special Precautions for the Eye Care Professional:

- 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 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.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Vision requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- 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 instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Before leaving the eye care professional's office, patients should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.

Lens Wearing Precautions:

- Check eyes daily to ensure they look well, feel comfortable and your vision is clear.
- Do not use if blister pack is damaged or not completely sealed. This may result in product contamination which can lead to a serious eye infection.
- The lenses are not intended to be cleaned or disinfected and should be discarded after a single use. Reuse can increase the risk of infection or fatigue-induced device failure.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- 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 your eye care professional before wearing lenses during sporting activities including swimming 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.
- Remove and discard lenses when exposed to noxious or irritating vapor.
- Discard a contact lens that has become dehydrated or damaged. Replace with a fresh new lens.
- It is recommended that contact lens wearers visit their eye care professional regularly as directed.
- Inform employer that you wear contact lenses, especially if job involves using eye protection equipment.
- Keep a note of the correct lens power for each eye. Before lens insertion, check that the lens power on each foil pack is correct for that eye.
- Be careful while using soaps, lotions, creams, cosmetics or deodorants as they can cause irritation if they come into contact with your lenses.
- Insert lenses before applying make-up and remove them before taking make-up off.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not use lenses after the expiry date.

ADVERSE REACTIONS (Possible problems and what to do)

Problems may occur with contact lens wear and may first present as one or more of the following signs and symptoms:

- Foreign body sensation (feeling of something in the eye)
- Uncomfortable lens
- Eye redness
- Sensitivity to light (photophobia)
- Burning, stinging, itching or watering eyes
- Reduced sharpness of vision
- Rainbows or halos around lights
- Increased eye secretions
- Discomfort or pain
- Severe or persistent dry eyes

These symptoms, if ignored, may lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS

- If any of the above signs or symptoms occur:
 - Immediately remove the lens(es).
 - Inspect the affected eye(s) in a mirror looking for signs of irregularity.
 - If the sign or symptom stops, insert a fresh, new lens.
 - If the sign or symptom persists or if it returns after insertion of a new lens(es), remove the lens(es) and immediately contact your eye care professional.
 - A serious condition such as infection, corneal ulcer (ulcerative keratitis), or iritis may be present.

- These conditions could progress rapidly and may lead to permanent loss of vision.
- Less serious reactions such as abrasions, epithelial staining and bacterial conjunctivitis must be managed and treated early to avoid complications.
- Occasional dryness may be relieved by blinking fully several times or by the use of contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your eye care professional.
- If a lens sticks (stops moving), apply several drops of a contact lens rewetting solution and wait until the lens begins to move freely on the eye. If this problem persists, consult your eye care professional.
- If a lens decenters on the eye, it may be possible to recenter it by:
 - o Closing your eyelids and gently massaging the lens into place, or
 - o Looking in the direction of the lens and blinking gently, or
 - o 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 your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help, contact your eye care professional for assistance.

DIRECTIONS FOR USE

Start each day with a fresh pair of lenses that are discarded at the end of every daily wearing period.

LENS HANDLING INSTRUCTIONS

- Always wash and rinse your hands thoroughly and dry with a clean, lint free towel before handling contact lenses.
- Shake the blister pack gently prior to opening.
- Remove the lens from the blister pack by carefully pouring it onto the palm of your hand.
- Ensure the lens is right side out and that you have the correct lens for each eye.
- Inspect the lenses prior to insertion. Insert lenses only if they appear to be clean and undamaged.

LENS INSERTION INSTRUCTIONS

- Wash and rinse your hands thoroughly and dry with a clean, lint free towel before handling contact 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 release the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

LENS REMOVAL INSTRUCTIONS

- Wash and rinse your hands thoroughly, and dry completely with a clean, lint free towel.
- 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 your fingers once more and try again. Do not use rewetting drops in this instance.
- Never use tweezers, suction cups, sharp objects or your finger nails to remove lenses from the lens container or your eyes.

If you experience problems with lens removal (lens decentered or damaged), see **WHAT TO DO IF A PROBLEM OCCURS** above.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic blister pack, which contains 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. The package is marked with the base curve, diameter, dioptric power, ADD power (where applicable), manufacturing lot number and expiration date.

Lenses are supplied in cartons containing up to 90 individually sealed contact lenses.

REFERENCES

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;321(12):773-83.

SYMBOLS USED ON LABELING

SYMBOL	ENGLISH
BC	Base Curve
DIA	Diameter
PWR	Power
D	Diopter (lens power)
ADD	Addition power
LO	Low
MED	Medium
HI	High
L	Left
R	Right
	Packaging waste license sign
	Do not reuse
	Batch code
	Use by
	Steam sterilized
	Caution
	Do not use if blister package is damaged
	Manufacturer
	Authorized Representative in the European Community
	Consult instructions for use
	Caution: Federal Law (United States) restricts this device to sale by or on the order of a licensed eye care professional
	European conformity sign



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Available Lens Parameters

Chord Diameter: 14.1mm

Center Thickness: 0.09mm @ -3.00D (varies with power)

Base Curve and Powers:

Spherical Lenses:

- Base Curve: 8.5mm
 - o Minus Powers: -0.50 to -6.00D (0.25D steps); -6.50 to -12.00D (0.50D steps)
 - o Plus Powers: +0.50 to +6.00D (0.25D steps)

Multifocal Lenses:

- Base Curve: 8.5mm
 - o Minus Powers: -0.25 to -10.00D (0.25D steps)
 - o Plus Powers: plano to +6.00D (0.25D steps)
 - o ADD: LO, MED, HI

ACTIONS (Mode of Action)

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

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