

Daily Disposable Soft Contact Lenses

CAUTION

Federal (U.S.A) law restricts this device to sale or on the order of a licensed practitioner.

IMPORTANT

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses and recommended wearing schedule.

Long term exposure to UV radiation is a part of the risk factors associated with cataracts. Exposure is according to a number of factors for instance environmental conditions (geography, altitude) and personal factors (nature of outdoor actives). UV blocking contact lenses help to resist harmful UV radiation. In any case, clinical studies have not proved that wearing UV blocking contact lenses decrease risk factor associated with cataracts.

DESCRIPTION

The material Etafilcon A is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid (MAA). The copolymer consists of 42% Etafilcon A and 58% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visibility-handling tint, color additive "reactive Blue19" , 21 CFR part 73.3121. The Etafilcon A name has been adopted by the United States Adopted Names Council (USAN). A benzotriazole UV absorbing monomer is used to block UV radiation. The handling tint is reactive blue 19, making the lens more visible when handing. The Daily Disposable Soft Contact lenses tint may reduce slightly after repeated disinfection. Slight reduction in tint will not affect the safety or performance of the lens. (Note if one day there will be no disinfection)

The physical/optical properties of the lens are:

Refractive index: 1.402 Light Transmittance: 95% minimum. Water Content: 58%

The Daily Disposable Soft Contact Lenses are a hemispherical shell of the following dimensions:

Sphere & Aspheric

- * Diameter: 12.0~15.0mm (±0.2mm)
- * Center Thickness:
 - Minus lenses - 0.06~0.14mm (±0.02mm)
 - (e.g., -3.00D : 0.08mm±0.02)
 - Plus lenses - varies with power
 - (e.g., +3.00D : 0.20mm±0.02)
- * Base Curve: 7.85~10.0mm (±0.2mm)
- * Power: +20.00D ~ -20.00D

Color: Tint Blue, Black, Brown, Blue, Green, Violet, Gray, Orange, Red, Gold, Pink, Yellow, White and Each Combination of above

INDICATION

Daily Disposable Soft Contact Lenses are indicated for daily wear for vision correction of refractive ametropia in aphakic or non-aphakic persons with non-diseased eyes that are myopic and hyperopic. The lens may be worn by people who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

Eye care practitioner may prescribe the lens for single-use daily disposable wear.

WARNING:

UV absorbing contact lenses aren't substitutes for protective UV absorbing eyewear for example UV absorbing goggles or sunglasses because they don't completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Daily Disposable 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 that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Any active corneal infection (bacterial, fungal, or viral).
- 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, such as scarring and ulceration of the cornea resulting in loss of vision. It is essential that patients strictly compliance with the eye care practitioner's direction and all labeling instructions for correct use of lenses and lens care products.
- Studies have shown that contact lens wearers who are smokers have a higher risk lens reactions than non-smokers, especially when lenses are worn overnight or while sleeping.
- If a patient experiences eye discomfort, such as foreign body sensation, excessive tearing, vision changes, or redness of the eye or other problems. The patient should immediately remove lenses and promptly contact his or her eye care practitioner.

- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions are increased when lenses are worn overnight.

- Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.

(NOTE NO CLEANING FOR DAILY LENSES)

HANDLING OF LENSES

Verify that the lens is right-side out. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.



Lens Orientation Correct



Lens Orientation Incorrect (Lens Inside Out)

PRECAUTIONS

Special Precautions for Eye care Practitioner:

- Due to the small number of patients enrolled in 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 practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, 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 eye should be carefully monitored by the prescribing eye care practitioner.
- Fluorescein, a yellow dye, should not be used while the patient is wearing the lenses, because the lenses will absorb this dye and become discolored. Whenever fluorescein is used in eye, flush the eyes with sterile saline solution. Wait at least 10 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait at least 1 hour before wearing the lenses. If inserted too soon, the lenses may absorb the remaining fluorescein.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have somebody else available who can remove the lenses for him or her.
- Eye care practitioner should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye care practitioner should carefully instruct patients about the following care regimen and safety precautions: (NO SOLUTIONS FOR DAILY LENSES)

- If the lens sticks (stops moving) on the eye, follow the recommended directions in Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, aerosol products or hair sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.
- Carefully follow the handling, insertion, removal, instructions in the Patient Information Booklet.
- 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. Ask your eye care practitioner about wearing contact lenses during sporting activities.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens blister pack unless specifically indicated for that use. Pour the lens onto the palm.
- Do not touch the lens with fingernails.
- Always discard lenses after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Do not use lenses past the expiration date.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, 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.
- Oral contraceptive users could develop visual change or change in lens tolerance when using lenses.
- Do not use if the sterile blister package is opened or damaged.
- Never allow anyone to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increase the chance of eye infections.

ADVERSE REACTIONS (Problem and What To Do)

The patient should be informed that the following problems may occur when wearing contact lenses:

- Your eye stinging, burning, itching (irritation), or other eye pain.
- Comfort is less compared to when lens was first placed on eye.
- There may be feeling of something in the eye (foreign body, scratched area).
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Feeling of dryness.
- Foreign body sensation.

If the patient notices any of the above, he or she should be instructed to:

- Immediately remove lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appear undamaged, the patient should thoroughly clean, and rinse, the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.
- If the above symptoms continue after removal of the lens, or upon insertion of the new lens, the patient should immediately remove the lens and contact his or her eye care practitioner or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious eye damage. 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.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing the contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

FITTING

- The lens must move adequately on the eye for a suitable fit. If the fit is judged to be too tight, the patient must be refit into the lens which provides the criteria of the well-fitted lens.
- Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.
- It is strongly recommended that the patient be provided the appropriate Patient Information Booklet available from PEGAVISION and understands its contents prior to dispensing the lenses.

WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

Daily Wear: There may be a tendency for the **NEW** daily wear patient to over-wear the lenses initially. Initial daily wearing schedule should be stressed to these patients.

The wearing schedule should be determined by the eye care practitioner. The maximum suggested wearing time for the Daily Disposable Soft Contact Lenses is:

DAY	1	2	3	4	5	6
HOURS	5	7	10	12	14	All waking hours

Wearing contact lenses is not safe during sleep.

FREQUENT / PLANNED REPLACEMENT

In a planned replacement program, the replacement schedule is determined by the eye care practitioner based upon the patient's physiological condition. PEGAVISION recommends the following replacement schedule for these lenses when prescribed in a Planned Replacement Program: (The eye care practitioner may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary.)

- Daily Disposable Soft Contact Lenses:

Replace every day

Wearing schedules (NOTE SEE WEARING TIME)

Daily Wear Contact Lenses	Water Content	Disposable program	UV block	Wear
Daily Disposable Soft Contact Lenses	56%	1 Day	Yes	Daily

LENS CARE DIRECTIONS

- **Daily** lenses are discarded upon removal from the eye **each day**.

- **Daily** Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Planned Replacement:

- Patients must adhere to a recommended care regimen. Failure to follow the complete regimen in accordance with manufacturer's package inserts and patient instructions may contribute to problems and/or result in the development of serious ocular complications as discussed in WARNINGS

Eye care practitioner should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient: General Lens Care and Basic Instructions.

LENS CARE PRECAUTION

The following solutions are recommended lens care solution for use with Daily Disposable Soft Contact Lenses. Eye care practitioner should review with the patient lens care directions, including both basic lens care information and specific instruction on the lens care regimen recommended for the patient.

Basic Instructions:

Care of contact lenses takes very little time to keep your eyes healthy.

- When lenses are dispensed, the eye care practitioner should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.
- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Lens Care Regimen:

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the Daily Disposable Soft Contact Lenses. Failure to follow this procedure may result in development of serious ocular infections.

Care for A Dried Out (Dehydrated) or Dry Lens:

If the soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle.

Warning: If disposable lens dry out completely, please discard immediately.

Care for A Sticking (Non-moving) Lens:

If the lens sticks (cannot be moved), you should use a lubricating or rewetting solution in your eye. You should apply 3 to 4 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 15 minutes, you should IMMEDIATELY consult your eye care practitioner.

Storage:

- All lenses that have been opened must be disinfected after each fitting and at least once each week. Unopened lenses are sterile and need not be disinfected until the vial seal has been broken.
- The Daily Disposable Soft Contact lenses must be stored only in the recommended solution.
- Always keep your lens completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn.
- If the lens dehydrates, reference the above section on care for the dried out (dehydrated) or dry lens.
- Storage and transport of product is in room temperature.
- Please keep at room temperature to avoid exposure to sunlight.
- If the lens is accidentally stored over the storage temperature (5–35 °C), such as in the car at noon on summer or freezing, short-term storage temperature does not affect the lens function and aseptic packaging, but does not mean that it can exceed the storage temperature for several weeks or several months. If there is over the storage temperature, please use these lenses first. Please return to room temperature before opening the sterile package, and confirm whether the aseptic package leaks. If it leaks, please discard the lens and avoid using it.

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 THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each Contact Lens is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter and expiration date on the blister pack label.

PEGAVISION Corp. 2F-1 No.5, Shing Yeh St., Guishan Dist., Taoyuan City 333, Taiwan

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Product certification Notify Body number: 2460		See Instruction Leaflet
	Batch code		Sterilized Using Steam
	Use by Expressed as: CCYY-MM- or CCYY-MM-DD YYYY-MM		CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.
	UV-Blocking (The mark is showing functional of UV blocking)		Consult instructions for use
	Diopter (Lens Power)(product property)		Center thickness (product property)
	Manufacturer		Base Curve (product property)
	Do not re-use		Diameter (product property)
	Lens Orientation Correct		Lens Orientation Incorrect (Lens Inside Out)