



OCYLENS (ETAFILCON A) DAILY DISPOSABLE SOFT (HYDROPHILIC) CONTACT LENSES

Visibility Tinted with UV Blocker
for Daily Wear Single Use Only

PACKAGE INSERT

IMPORTANT : 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 and recommended wearing schedule.



CAUTION: The US federal law restricts this device to sale by or on the order of a licensed eye care practitioner.

DESCRIPTION

The OcyLens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are available in a spherical design. The OcyLens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are made of a hydrophilic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and Methacrylic Acid (MAA). When hydrated, the lenses consist of 42% (etafilcon A) and 58% water by weight when immersed in buffered saline. 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. A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking averages 95% in the UVB range of 280 nm to 315 nm and 50% in the UVA range of 316 nm to 380 nm. The etafilcon A name has been adopted by the United States Adopted Names Council (USAN).

LENS PROPERTIES

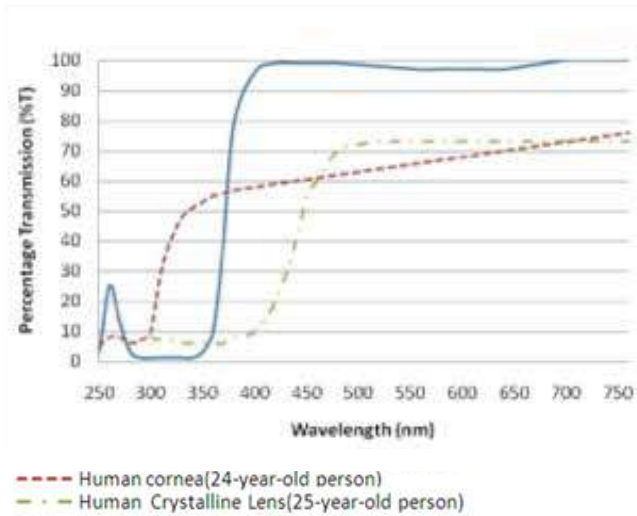
Refractive index : 1.402
Water Content : 58%
Oxygen Permeability (Dk) : 19.73x10⁻¹¹ (cm²/s){mlO₂ml/(ml x mmHg)}
Light Transmittance : > 95%

LENS PARAMETERS

Sphere and Asphere Lens parameters :
Diameter : 12.0mm ~ 15.0mm
Center Thickness : 0.08 @-3.00D (varies with power)
Base Curve: 7.80mm ~ 10.00mm
Powers : +20.00D to -20.00D

TRANSMITTANCE CURVE

Typical Transmittance Profile of -3.00D OcyLens (etafilcon A) Contact Lenses with UV blocker versus a human cornea from a 24 year-old person and a human crystalline lens from a 25 year-old person.



Note:

1. Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58, Figure 2-21.
2. Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.



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.

ACTIONS

In its hydrated state, the OcyLens (etafilcon A) Contact Lenses, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The visibility tinted OcyLens (etafilcon A) Contact Lenses allow the lens to become visible to the wearer when the lens is not on the eye. The OcyLens (etafilcon A) Contact Lenses blocks 50% of UVA radiation and 95% of UVB radiation average across the spectrum. (Please refer to accompanying transmittance curve graph)

Note : 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 (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care professional for more information.

INDICATION

Spherical and Aspherical
The OcyLens (etafilcon A) SPHERE and ASPHERE Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters. The lenses may be worn by persons who exhibit

astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The OcyLens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye. The lenses are intended for single-use disposable wear.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the OcyLens Lens when any of the following conditions exist:

- Acute and sub-acute 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.
- Use of any medication that is contraindicated or interferes with contact lens wear, including ocular medications.
- Allergy to any ingredient in the contact lens material.
- History of recurrent eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or an unusual response to contact lens wear.
- The patient is unable or unwilling to follow the eye care professionals' directions for removal and disposal of the lenses or unable to obtain assistance to do so.

WARNINGS

Advise patient of the following warnings pertaining to contact lens wear:

- Problems with contact lenses 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.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers), can develop rapidly and lead to loss of vision.
- Studies have shown that contact lens wearers who are smokers have a higher risk incidence of adverse 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 professional.
- 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 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.

- Tap water, distilled water, homemade saline solutions or saliva should NOT be used at any time with contact lenses. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.

PRECAUTIONS

Special Precautions for Eye Care Professional:

- 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 professional 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 professional.
- 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 and remain fluorescein.
- Before leaving the eye care professional'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 Professional should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye care professional should carefully instruct patients about the following safety precautions, including the need for routine eye examinations being necessary to help assure the continued health of the patient's eyes:

(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 professional.
- 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.

- 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 the eye care professional about wearing contact lenses during sporting activities.
- Never wear lenses beyond the period recommended by the eye care professional.
- 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.
- Aphakic patients should not be fitted with lenses until the determination is made that the eye has healed completely from surgery.
- Inform the doctor (eye care professional) 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 into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses after the recommended wearing schedule prescribed by the eye care professional.
- Always contact the eye care professional 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.
- Patients who are pregnant or 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.
- Diabetics may have reduced corneal sensitivity and may be more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Patients who wear contact lenses to correct presbyopia may not achieve the best correct 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.
- Patients should be instructed to never allow anyone to wear their lenses. They have been prescribed to fit their eyes and to

correct their 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 appears 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 professional.
- If the above symptoms continue after removal of the lens, or upon insertion of a new lens, the patient should immediately remove the lens and contact his or her eye care professional 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.
- Patients should be reminded to keep a spare pair of lenses with them at all times.

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 a contact lens on the affected eye when examined, the lens should be removed immediately.

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 a lens which provides the criteria of a well-fitted lens.
- Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.
- Copies of Profession Fitting and Information Guide for OcyLens Lenses are available without charge from www.ocyvision.com

WEARING SCHEDULE

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

Daily Wear (Less than 24 hours, while awake):

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 professional. The maximum suggested wearing time is:

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	All waking hours

The OcyLens Lenses are only indicated for daily wear (less than 24 hours, while awake). The OcyLens Lenses should NOT be worn for 24 hours or greater, including while asleep, as studies have not been completed to show that the lenses are safe to wear during sleep.

REPORTING OF ADVERSE REACTION

If any serious adverse events or a patient experiences associated with the wear of the OcyLens (etafilcon A) Daily Soft (Hydrophilic) Contact Lenses, please report to Pegatron Corporation, located at 800 Corporate Way, Fremont, CA 94539, USA, Toll Free Number: 1(877) 636-3092

FREQUENT / PLANNED REPLACEMENT

OcyLens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses: Replace every day. Wearing schedules (NOTE SEE WEARING TIME)

Daily Wear Contact Lens	Water Content	Disposable Program	UV Block	Wear
OcyLens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses	58%	1 Day	Yes	Daily

LENS CARE DIRECTIONS

- Daily lenses are discarded upon removal from the eye each day.
- Patients should be instructed to have a spare pair of lenses with them at all times.

Care for A Sticking (Nonmoving) 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 professional.

Storage:

- Unopened lenses are sterile and need not be disinfected until the container is broken or the seal has been damaged.
- Storage and transport of product is in room temperature.

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 PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing borate buffered saline solution with Tween 80, Sodium Hyaluronate and Polyethylene Glycol. The blister is labeled with the base curve, diameter, diopter power, manufacturing lot number, and expiration date of the lens. (ADD, cylinder and axis will be included as appropriate.)

Manufactured by



PEGAVISION CORP.
2F-1, NO. 5, SHING YEH STREET, GUSHAN DISTRICT, TAOYUAN CITY 33, TAIWAN (R.O.C)

Imported and Distributed by

WESTERN BIOTECH LLC
500 MERCER STREET, C202-122A, SEATTLE, WA 98109, USA
E-mail : contact@westernbiotech.com

For SYMBOL DESCRIPTION, please refer to the OcyLens Patient Instruction Guide.



www.ocyvision.com