## 1-DAY OCYLENS (ETAFILCON A) DAILY DISPOSABLE SOFT (HYDROPHILIC) CONTACT LENSES

Hydrogel, etafilcon A, Aspheric







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

#### **SPECIFICATION**

Brand Name	1-Day Ocylens
Lens Material	etafilcon A
FDA Classification	Group IV, Water > 50%, Ionic
Surface Character	Hydrophilic
Water Content	58%
Base Curve	8.5 mm ± 0.2 mm
Diameter	14.2 mm ± 0.2 mm
Center Thickness	0.08 ± 0.02 mm @ -3.00D, varies with power
Refractive Index	1.402
Light Transmittance	> 95%
Oxygen Permeability (Dk)	19.73x10 <sup>-11</sup> (cm2/s){ml02ml/(ml*mmHg)}
Dk/t	25x10 <sup>-9</sup> (cm2/sec) [ml02/(ml x mmHg)] @ -3.00D
Power Range	+4.00D to - 12.00D
Replacement Schedule	Daily Disposable
Packaging	2 lenses per pack and 30 lenses per pack
<b>UV Protection</b>	Class II - blocks at least 70% UVA and 95% UVB radiation

#### **INDICATIONS**

The 1-Day Ocylens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive 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.

Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required. The 1-Day 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.

# Superb Visual Performance. Easy to Fit. Extremely Low Body Sensation.

### Our Lens Material **Etafilcon A**

















#### **LENS MATERIAL**

The 1-Day Ocylens (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are made from a hydrogel etafilcon A material. The lens material (etafilcon A) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and Methacrylic Acid (MAA).

#### HIGH WATER CONTENT

When hydrated, the lenses consist of 42% (etafilcon A) and 58% water by weight when immersed in buffered saline.

#### **UVA/UVB PROTECTION**

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.

#### **SUPER EDGE DESIGN**

Ocylens provides a patient with greater satisfaction due to its smooth edge design and extremely low body sensation.

#### **MOISTURIZING**

Ocylens' Hyaluronic Acid multi-layer moisturizing agent offers not only a greater comfort and moisture, but also removes substances which might cause discomfort.

#### **HIGH DEFINITION (HD)**

With Ocylens High Optical Design Technology, our aspheric lens design ensures visual acuity with high definition.

#### **U.S. FDA ESTABLISHMENT REGISTRATION**

- Manufacturer: Pegavision Corporation, Registration and FEI No. 3010392968.
- Importer and Distributor: Western Biotech LLC. Registration and FEI No. 3013987845. Owner/Operator No. 10055781.

#### **U.S. FDA MEDICAL DEVICE LISTINGS**

- Ocylens, LPL & MVN, Regulation No. 886.5925, Premarket Submission No. K161739

#### **CERTIFICATIONS**

- Good Manufacturing Practice (GMP), based on ISO 13485. Registration No. GMP0758
- EC Certificate for Full Quality Assurance System. Certificate No. 10366-2017-CE-RGC-NA-PS Rev. 0.0.
- ISO 13485 : 2003/NS-EN ISO 13485 : 2012. Certificate No. 240156-2017-AQ-RGC-NA-PS Rev. 0.0.
- Other certificates include Japan FMA, Taiwan TFDA, China CFDA etc.



Manufactured by

#### PEGAVISION CORPORATION

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Pegavision Corp. is listed in Taiwan stock exchange and founded in 2009 as a joint venture of Kinsus and Pegatron – one of the world's largest electronic companies with annual revenue exceeding US\$ 40 billion.

Imported and Distributed by

#### **WESTERN BIOTECH LLC**

500 Mercer Street, C202-122A, Seattle, WA 98109, USA www.ocyvision.com

E-mail: contact@westernbiotech.com

If any serious adverse events or patient experiences related to our products, please report to **PEGATRON CORPORATION**, 800 Corporate Way, Fremont, CA 94539, USA; Toll Free Number: 1(877) 636-3092

Contact us today for FREE TRIAL LENSES.



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