

SYMBOLS KEY	
The following symbols may appear on the label or carton:	
SYMBOL	DESCRIPTION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	CE Mark and Identification number of Notified Body
	UK Conformity Assessment Marking and Identification Number of Notified Body
UV BLOCKING	UV Blocking
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF THE PATIENT EXPERIENCES:

- Eye Discomfort
- Excessive Tearing
- Vision Changes
- Loss of Vision
- Eye Redness
- Other Eye Problems

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.

- When prescribed for daily wear, patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.³
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

³New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

SYMBOL	DESCRIPTION
	Authorized Representative in the European Community
	Contains Hazardous Substances
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged
MD	Medical Device Symbol
	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
	UV Blocking
	Fee Paid for Waste Management
	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner
A	ACCENT STYLE
N	NATURAL SHINE®
V	VIVID STYLE

Visit www.acuvue.com/guides for additional information about symbols.

Specific Instructions for Use and Warnings:

- **Water Activity**

Instruction for Use

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submerged in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- 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 the eye should be carefully monitored by the prescribing Eye Care Professional.

DESCRIPTION

The 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® Technology are soft (hydrophilic) contact lenses available as spherical lenses. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate.

The 1-DAY ACUVUE® DEFINE® Brand Contact Lenses are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. The lenses contain a pigmented area that will alter or enhance the appearance of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, and Reactive Blue Dye #4.

The 1-DAY ACUVUE® DEFINE® Contact Lenses are available in the following variants (i.e., patterns):

- **ACCENT STYLE**
- **NATURAL SHINE**
- **VIVID STYLE**

A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking averages 97% in the UVB range of 280 nm to 315 nm and 81% in the UVA range of 316 nm to 380 nm.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 - 1.13
- Refractive Index: 1.40
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 58%
- **Oxygen Permeability (Dk):**

VALUE	METHOD
21.4 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /mL x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)
28.0 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /mL x mm Hg) @ 35°C	Fatt (boundary corrected, non-edge corrected)

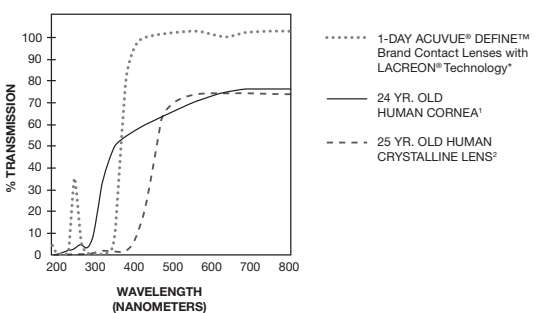
AVAILABLE LENS PARAMETERS

The 1-DAY ACUVUE® DEFINE® Contact Lenses are hemispherical shells of the following dimensions:

- Diameter (DIA):** 14.20 mm
- Center Thickness:** Low minus lens-varies with power (e.g., -3.00D, 0.084 mm)
Plus lens-varies with power (e.g., +1.00D, 0.130 mm)
- Base Curve (BC):** 8.5 mm
- Powers (D):** -9.00D to -6.50D (in 0.50D increments)
-6.00D to -0.25D (in 0.25D increments)
0.00 to +1.00D (in 0.50D increments)

TRANSMITTANCE CURVE

1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® Technology vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



* The data are representative measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.00D lens, 0.084 mm center thickness).

¹Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

²Waxler, M. Hitchens, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The UV Blocking for 1-DAY ACUVUE® DEFINE® Contact Lenses averages 97% in the UVB range of 280 nm to 315 nm and 81% in the UVA range of 316 nm to 380nm for the entire power range.

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. The Eye Care Professional should be consulted for more information.

INDICATIONS (USES)

The 1-DAY ACUVUE® DEFINE® Contact Lenses are indicated for daily disposable wear to enhance or alter the appearance of the eye. These lenses are also indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all Doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their 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.

ADVERSE REACTIONS

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

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The 1-DAY ACUVUE® DEFINE® Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

These lenses should be prescribed for daily disposable use only. No cleaning or disinfection is required. Lenses should be discarded upon removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these lenses when any of the following conditions exist:

- Acute or 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 eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

GENERAL FITTING GUIDELINES

A. Patient Selection

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.