

OCuSOFT® AMENITY™

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™



PATIENT INFORMATION BOOKLET

Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patient's prescribed lens.

FOR SINGLE USE DISPOSABLE WEAR



CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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R10/23

PATIENT INFORMATION BOOKLET

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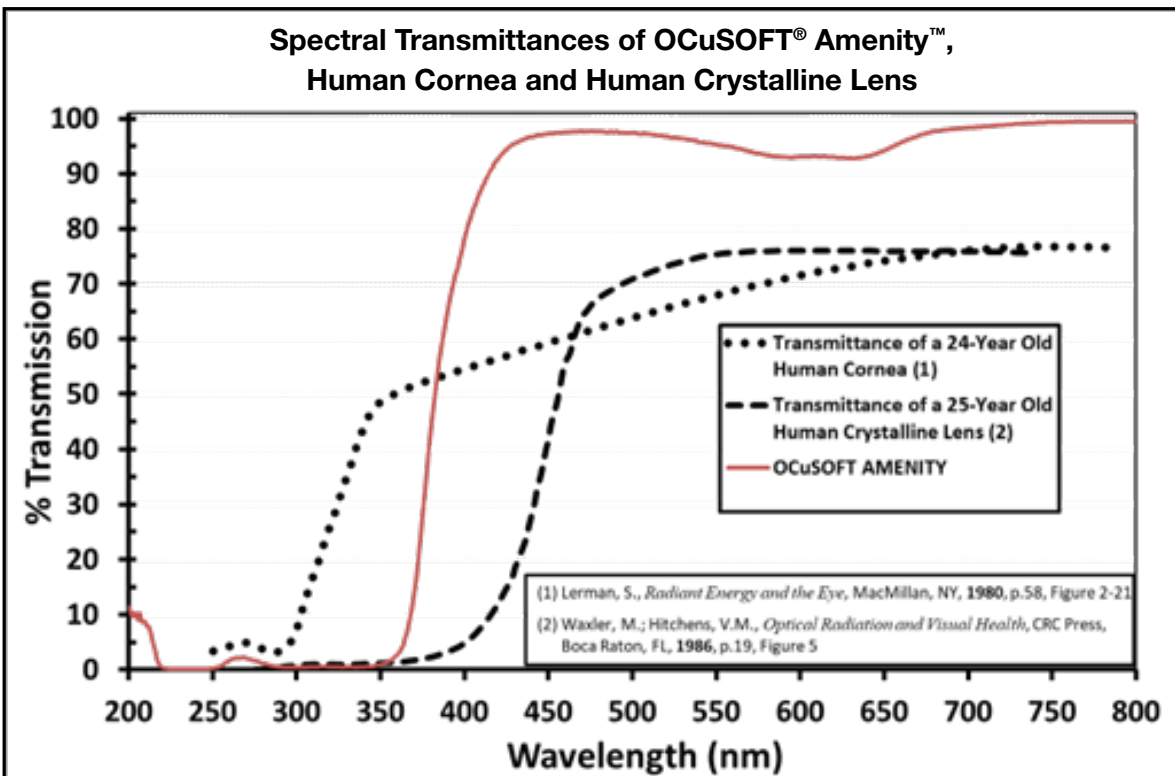
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DESCRIPTION

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are a hemispherical shell with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lenses. The lenses are fabricated from linofilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 62.0% linofilcon A and 38.0% water by weight when immersed in saline solution. The linofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ contain C.I. Reactive Blue No. 19 (21 CFR Part 73.3127) for visibility and handling.

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ incorporate a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation. The lens blocks >95% in the UVB range (280nm - 315nm), and >70% in the UVA range (316nm - 380nm). Refer to the following transmittance profile for the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™



Note: the above % transmission data are based on measurements from a -3.00 D lens. The data was obtained from measurements with a spectrophotometer taken through the central 3-5 mm portion of the lens.

The following table lists the material properties and available parameters for the **OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™**.

Parameter	Range	Tolerance*
Chord Diameter	13.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.080 mm @ -3.00 D	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.00 mm to 9.50 mm	±0.20 mm
Back Vertex Power (F'v)	+20.00D to -20.00D	When $0.00 < F'v \leq 10.00$ D → ±0.25 D When $10.00 < F'v \leq 20.00$ D → ±0.50 D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10-11(cm2/sec)(mlO2)/(ml x mmHg))	100	±20%
Light Transmittance - Tinted (@ 380-780nm)	95%	±5%
Ultraviolet Radiation Transmittance	< 5 % TUVB < 30 % TUVA	TUVB (280 to 315 nm) < 0.05Tv TUVA (316 to 380 nm) < 0.50Tv
Water Content	38%	±2%
Refractive Index	1.415 (hydrated)	±0.005

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties (2016)

ACTIONS

In the hydrated state, the **OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™** when placed on the cornea, act as refracting media to focus light rays on the retina.

INDICATIONS

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and 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 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ when any of the conditions are present:

- 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), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients are unable to follow, or to obtain assistance to follow, lens care regimen.

WARNINGS

Problems with contact lenses could result in serious injury to the eye.

- Water can harbor microorganisms that can lead

to severe infection, vision loss or blindness. If the patient's lenses have been submersed in water, such as when swimming in pools, lakes, or oceans the patient should discard them and replace them with a new pair. Patients should be instructed to ask their eye care practitioner (professional) for recommendations about wearing their lenses during any activity involving water.

- 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
 - Or Other Eye Problems

The patient should immediately remove the lenses, and promptly contact their eye care practitioner.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- All contact lens wearers must see their eye care practitioner as directed.

PRECAUTIONS

Special Precautions for the Eye Care Practitioner:

- Clinical studies have demonstrated that contact lenses manufactured from (linofilcon A) are safe and effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of the lens, 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 the eye should be carefully monitored by the prescribing eye care practitioner.

- Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens absorbs this dye and becomes discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lens or should have someone else available who can remove the lens for him or her.
- Eye care practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.
- The patient should be instructed to always discard lenses after removal.
- If the lenses are prescribed for disposable wear, they are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. If a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Carefully follow the handling, insertion, removal, emergency care instructions in the daily disposable patient instructions for the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ and those prescribed by the eye care practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving lens). The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to IMMEDIATELY consult his or her eye care practitioner.
- Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-based cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask the eye care practitioner about wearing lens during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with your fingernails.
- Always contact the eyecare practitioner before using any medicine or medications in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that the patient not wear contact lens.
- 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.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive water (tearing) of the eye.
- Unusual eye secretions.
- Redness of the eye.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

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

- Immediately remove and discard the lens. Do not put the lens back on the eye. If the problem continues, the patient should immediately consult an eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to Keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

All serious adverse reactions observed in patient's using the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ should be reported to:

OCuSOFT Inc.
30444 Southwest Freeway
Rosenberg, TX 77471
(800) 233-5469 | www.ocusoftlenses.com

FITTING

For a detailed description of the fitting techniques, refer to OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ Professional Fitting and Information Guide, copies of which are available from:

OCuSOFT Inc.
30444 Southwest Freeway
Rosenberg, TX 77471
(800) 233-5469 | www.ocusoftlenses.com

WEARING SCHEDULE

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are to be worn during the daytime hours as instructed by an eye care professional and discarded after each removal.

Studies have not been completed to show that OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are safe to wear during sleep.

LENS CARE DIRECTIONS









For complete information and instruction concerning Daily Disposable lenses refer to OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ Patient Instruction/Wearer's Guide.

HOW SUPPLIED:

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are sterile in sealed blister packages containing a buffered saline solution. The base of the package is made from polypropylene, which is covered with an aluminum foil seal. The blister packages are marked with the base curve, diameter, dioptric power, cylinder power, cylinder axis, multifocal add power, lens color, manufacturing lot number, and expiration date.

SYMBOL GLOSSARY

Comprehensive guide to symbols appearing on product labels and cartons.

Symbol	Symbol Title	Symbol Description	Standard Reference	Title and Designation Number of the Standard
	Sterilized using steam	Indicates a medical device that has been sterilized using steam.	5.2.5	ISO 15223-1:2021 Medical device - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Do not re-use	Indicates a medical device that is intended for one single use only.	5.4.2	
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3	
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	5.4.4	
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	
	Recycle	Indicates that this item can be recycled.	N/A	
DIA	Total diameter	Indicates total diameter of lens.	N/A	
BC	Base curve	Indicates base curve of lens.	N/A	N/A
PWR	Paraxial back vertex power	Indicates lens power in diopters.	N/A	N/A
SPH	Sphere power	Indicates spherical power in diopters.	N/A	N/A
AX	Cylinder axis	Indicates axis of cylinder power in degrees.	N/A	N/A
CYL	Cylinder power	Indicates cylindrical power in diopters.	N/A	N/A
ADD	Additional power	Indicates additional power in diopters.	N/A	N/A
YYYY-MM	Effective date	Indicates the date in which the insert revision was made effective.	N/A	ISO 8601-1:2019 Date and time Representations for information interchange — Part 1: Basic rules
	Prescription only (USA)	Indicates that federal law (U.S.) restricts this device to sale by or on the order of a licensed practitioner.	N/A	21 CFR 801.109