

Instruction of ComfyArt Silicone Hydrogel One Day Soft Contact Lenses for User

ComfyArt Silicone Hydrogel One Day Soft Contact Lenses for Daily Wear Single Use Only

DESCRIPTION and LENS PARAMETERS

ComfyArt Silicone Hydrogel One Day (unifilcon a) Soft Contact Lenses for Daily Wear Single Use is a hydrophilic co-polymer of silicone containing monomers.

The lens has a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.6 ~ 14.6mm
- Centre Thickness: varies with power e.g. 0.07mm (at -3.00 DS)
- Base Curve: 8.2 ~ 9.4mm
- Sphere Powers:
 - 0.00D ~ -6.00D in 0.25D per step
 - 6.50D ~ -12.00D in 0.50D per step
 - +0.50D ~ +6.00D in 0.25D per step

The physical/optical properties of the lenses are:

- Surface Character: Hydrophilic
- Water Content: 43%
- Oxygen Permeability (DK): 60×10^{-11} (cm²/sec) (ml O₂/ml x mmHg) at 35°C±0.5 °C (Polarographic Method for determination of oxygen permeability).

INDICATIONS (USES)

The ComfyArt silicone hydrogel 1 DAY Soft Daily Disposable Contact Lens is indicated for daily wear 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 that does not interfere with visual acuity.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE your contact lenses if 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 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 that may be induced or

exaggerated by wearing contact lenses or use of contact lens solutions

- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

WARNINGS

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

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases are essential for the safe use of these products.

- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.

- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) is greater for people who wear extended wear contact lenses than for those who wear daily wear lenses. Do not wear your lenses while sleeping as the risk of sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.

- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove the lenses and promptly contact your eyecare practitioner. It is recommended that you see your eyecare practitioner routinely as directed.

- Water Activity – Do not expose your contact lenses to water while you are wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

- Reusing daily disposal contact lenses can increase the risk of infection, corneal ulcer and discomfort.

PRECAUTIONS

At your initial visit to your eyecare practitioner:

- Be sure you read and understand the full contents of this booklet and discuss it with your eyecare practitioner.

- Give your eyecare practitioner a complete history of your eye health, including any eye injuries, diseases, conditions or other problems you have had with your eyes, even if they seem unimportant to you.

- Tell your eyecare practitioner about your general health, any medicines you are taking, current treatment by a physician, any disease you had or now have and any prior surgery.
- Before leaving the eyecare practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses.

Lens Handling Precautions:

- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to cause damage lenses than oil base products.
- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle lenses gently and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand when removing from lens blister

Lens Wearing Precautions:

- You should remove your lenses immediately if your eyes become red or irritated.
- Never wear lenses beyond the period recommended by your eyecare practitioner.
- Always discard lenses worn as prescribed by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep your eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Avoid rubbing your eyes with the lenses on, this can irritate your eye or dislodge the lens.
- Keep your eyes closed tightly when washing or showering to keep water and soaps out of your eyes, these may cause loss of the senses, contamination or injury to your eyes.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Ask your eyecare practitioner whether there are any other wearing restrictions that apply to you.
- Daily disposal lenses are designed for single use only and should not be reinserted or stored once removed from the eye.

ADVERSE EFFECTS

Be aware that the following problems may occur when wearing contact lenses:

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

If you notice any of the above symptoms:

- Immediately remove the lenses.
- If the discomfort or problem stops, look closely at the lens.
- If the lens is in any way damaged, do not put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.
- If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.
- If the problem continues, you should not put the lens back on your eye but immediately consult your eye care professional.
- When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularisation or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

LENS CARE DIRECTIONS

1. Basic Lens Care Instructions

Remember there is no cleaning or disinfection needed with ComfyArt 1 Day soft contact lenses prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

2. Care For a Sticking (Non-Moving) Lens

If the lens stops moving or cannot be removed, you should be instructed to apply a few drops of the recommended lubricating solution directly to your eye and wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, you should immediately consult your eyecare practitioner.

3. Care for a Dehydrated Lens

If a soft, hydrophilic lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a fresh one.

4. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing isotonic saline solution. The blister pack is labelled with the base curve, diopter for spherical lenses or toric power, diameter, lot number, and expiration date of the product.

Do not use if blister pack has been broken or damaged.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients should be reported to:

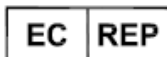
ApexLens Co., LTD.

Attn: Product Services

2F, No. 21, Shui Li Rd., Hsinchu 300, Taiwan, R.O.C.

+886-3-5752910













www.apexlens.com



Luana Med. B.V.

2627 AL, Abtswoudseweg 18, Delft, the Netherlands

Tel: +31 6 2025 4033

| | | | |
|--|----------------|--|---|
|  | Use by |  | Sterilized using steam or dry heat |
|  | Batch code |  | This device to prescription only |
|  | Manufacturer |  | Consult instructions for use |
|  | Do not reuse |  | Do not use if package is damaged |
|  | Caution |  | Authorized representative in the European Community |
|  | Medical device |  | Single sterile barrier system |