

ComCan Aqua Daily Disposable Silicone Hydrogel Contact Lens

DESCRIPTION

ComCan Aqua Daily Disposable Silicone Hydrogel Contact Lens for Daily Wear Single Use is a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with Trimethylpropane trimethylacrylate. The soft contact lenses are made from 48% water and 52% Unifilcon A and provided in sterile individual blister packages, with the lens immersed in phosphate buffered saline solution.

INTENDED PURPOSE




















ComCan Aqua Daily Disposable Silicone Hydrogel Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia) in phakic or aphakic persons with non-diseased eyes in powers from -10.00 to -0.50 diopters (D).

INDICATIONS

For the correction of refractive ametropia (myopia).

SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Barrier system		Single sterile barrier system Sterilized using steam or dry heat
	Diameter		Base curve
	Use by date		Diopter (lens power)
	Do not use if package is damaged and consult instructions for use		Power
	Do not re-use		Manufacturer
	Authorized representative in the European Community/European Union		Keep away from sunlight
	Prescription use only		Temperature Limit
	Medical device		Do not reinsert
	Unique device identifier		CE number
	Country of manufacture		

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

Lens Properties

- Refractive Index: 1.410
- Water Content: 48%
- Oxygen transmissibility(DK) : 60×10^{-11} (cm²/sec) (ml O₂/ml x mmHg) at 35°C
- DK/t = 86×10^{-9} (cm/sec)(ml O₂/ml x mmHg) Polarographic Method (Boundary and Edge Corrected)
- Transmittance: Light Transmittance > 90%
UVA (316-380nm) < 50%
UVB (280-315nm) < 5%

Lens Parameters

- Diameter Range: 13.5 to 14.5 mm
- Base Curve Range: 8.00 to 9.20 mm
- Spherical Power Range: -0.50 to -10.00 D

Lens Parameters Available

- Chord Diameter: 14.1 mm
- Base Curve: 8.50 mm
- Center Thickness: Minus lens - varies with power (e.g., -3.00D, 0.07mm)
- Powers: -0.50 to -10.00 D
-0.50 to -6.00 D (0.25 D steps)
-6.00 to -10.00 D (0.50 D steps)
- Shelf Life: 5 year

INSTRUCTION

- Daily disposal schedule: Please replace contact lenses every day.
- Function: The disposable contact lens is indicated to correct myopia.

Intended population

- Adult persons with myopia who require correction of refractive ametropia.

CONTRAINDICATIONS (when not to use)

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

- 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.

- 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 the 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 Eye Care Professional. It is recommended that you see your Eye Care Professional 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.
- 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.

PRECAUTIONS

At your initial visit to your Eye Care Professional:

- Be sure you read and understand the full contents of this booklet and discuss it with your Eye Care Professional.
- Give your Eye Care Professional 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 Eye Care Professional 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 Eye Care Professional's office, you should be able to promptly remove lenses or should have someone

else available who can remove the lenses.

Lens Handling Precautions:

- **Do not use** if the sterile blister package is opened or damaged. In order to ensure sterility, the blister package should not be opened until immediately prior to use.
- **Discard any lens which has become dehydrated or damaged.** Replace with a sterile, fresh, new lens. Don't resterilize.
- **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 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 Eye Care Professional.
- **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.

● **To insert lenses:**

1. Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
2. Carefully lift the tab using your thumb and index finger, then peel back the foil.



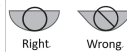
3. Scoop the contact lens out with the tip of your index finger. Make sure it's the right way round before putting it on.
4. Place a lens on the tip of your clean and dry right or left index finger, place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
5. Use the fingers of the other hand to lift the upper eyelid.
6. Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
7. Look down and slowly remove the hand, releasing the lower lid.
8. Look straight ahead and slowly remove the other hand, releasing the upper lid, and blink gently.
9. Use the same technique when inserting the lens for the other eye.

● **To remove lenses:**

1. Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. **Make sure hands are clean and completely dry.**
2. Blink fully several times.
3. While looking up, slide the lens down onto the white part of the eye.
4. Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
5. Remove the other lens by following the same procedure.

Lens Wearing Precautions:

- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Ensure that the correct lens for each eye is available, and ensure the lens is right side out. If the edges flare out, it's inside out. If it looks like a



smooth edged cup, it is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.

- You should remove your lenses immediately if your eyes become red or irritated.
- **Never** wear lenses beyond the period recommended by your Eye Care Professional.
- **Always** discard lenses worn as prescribed by your Eye Care Professional.
- 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 Eye Care Professional before using any medicine in the eyes.
- **Ask** your Eye Care Professional whether there are any other wearing restrictions that apply to you.

Follow-up visits to your Eye Care Professional:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Be sure to keep your follow-up appointments.
- When you return for follow-up visits, be sure to tell your Eye Care Professional if your eyes have felt dry, irritated or anything other than completely comfortable while wearing your contact lenses.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Patient should be cautioned

accordingly.

- If there is any question in your mind about your wearing schedule and restrictions, cleaning lens handling procedures, lens replacement programs, the condition of your lenses, your follow-up visit schedule, or anything else about contact lens wear, be sure to discuss the subject with your Eye Care Professional, who is there to help you and see you use your contact lenses safely and properly.
- If your Eye Care Professional puts a dye or drops in your eyes during the examination, ask when you may be reinserted the lenses. The use of most dyes or drops will require a waiting period before the lenses may be reinserted.

Who Should Know That the Patient is Wearing Contact Lenses?

- Inform your doctor (Health Care Professional) about being a contact lens wearer.
- 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.

ADVERSE EFFECTS

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

- The eye may burn, sting and/or itch (irritation).
- 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 and 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 (tearing), unusual eye secretions or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia or dry eyes may occur if the lenses are worn continuously or for too long a time.
- **Reusing daily disposable contact lenses have been shown to be associated with a higher risk of developing ocular complications, such as eye infection.**

If the patient reports any problems:

- IMMEDIATELY REMOVE THE LENS.
- If the discomfort or problem stops, the patient should then look closely at the lens.
- If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and place a new fresh lens on the eye.
- If the lens is dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.
- If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER Eye Care Professional.
- When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

WEARING AND APPOINTMENT SCHEDULE

Your Eye Care Professional should prescribe the lenses for daily wear single use, and determine the appropriate wear schedule

based upon your history and ocular examination.

- For the first-time wearers, the recommended wear schedule is:

Day	Hours
1	4-6
2	6-8
3	8-10
4	10-12
5 and after	Recommended maximum wear time is 14-16 hours.*

- * Sleeping 8 hours and waking up for 16 hours is the norm for healthy adults. Studies initiated by HOPE have not been completed to demonstrate that the lenses are safe to wear for more than 16 hours a day.
- Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following appointment schedule is a suggested guideline:
 - 24 hours post-dispensing
 - 7 days
 - 1 month
 - 3 months
 - Every 6 months thereafter

LENS CARE DIRECTIONS

1. Basic Lens Care Instructions

Eye Care Professional should review lens care directions with you, including basic lens care information. It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always, wash, rinse and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in your mouth.

- Never rinse your lenses in water from the tap. There are two reasons for this:

a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.

b. You might lose your lens down the drain.

- The blister package should not be opened until immediately prior to use.
- For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

Limitation on reuse (for daily wear, single use)

Remember there is no cleaning or disinfection needed with ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

Non-compliance with replacement of daily disposable contact lenses have been shown to be associated with a higher risk of developing ocular complications.

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 Eye Care Professional.

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 eye care professional or visit a hospital emergency room without delay.**

How Supplied

Each sterile lens is supplied in a foil-sealed plastic package containing phosphate buffered saline solution. The plastic package is marked with base curve, diameter, diopter power, manufacturing lot number and expiration date.

Storage

The blister package should not be opened until immediately prior to use, and keep them in room temperature (15 to 25°C). Lenses in a solution shouldn't be storage or exposed to extreme temperatures and direct sunlight.

Disposal Method

- Outer packaging can be recycled with your standard household recycling.
- Dispose your contact lenses in solid waste bins, and avoid throwing them into the sink or the toilet.

REPORTING OF ADVERSE REACTIONS:

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

Manufacturer

Hope Vision CO., Ltd. Attn: Product Services
No.69, Quanyi Rd., Zhunan Township,
Miaoli County 35059, Taiwan (R.O.C.)
(886)37-585-285 www.hope-vision.com

Authorized representative in the European Community

Mdi Europa GmbH Langenhagener Str. 71
D-30855 Langenhagen, Germany

