

ComCan Puriti Plus Disposable Silicone Hydrogel Contact Lens

DESCRIPTION

No	Product name	Model
1	ComCan Puriti Plus Disposable Silicone Hydrogel Contact Lens	ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens
2	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens

ComCan Puriti Plus Disposable Silicone Hydrogel Contact Lens are hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with Trimethylpropane trimethylacrylate. The soft contact lenses are made from 43% water and 57% Unifilcon A and provided in sterile individual blister packages, with the lens immersed in phosphate buffered saline solution.

INTENDED PURPOSE

ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens and ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens with UV blocker are indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes in powers from -10.00 to +6.00 diopters(D).

ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens is indicated for daily wear a day.

ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens is indicated for daily wear a month.

INDICATIONS

For the correction of refractive ametropia (myopia and hyperopia).

SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Batch code		Sterile using steam heat
	Caution		Diameter
	Consult instructions for use		Base curve
	Use by date (expiration date)		Dioptric (lens power)
	Do not use if package is damaged		Power
	Do not reuse		Manufacturer
	Authorized representative in the European Community		Keep away from sunlight
	Prescription use only		Temperature Limit
	Do not re-sterilize		

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

LENS SPECIFICATION

- Items:ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens ` ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens
- Wearing schedule: Daily Disposable ` Monthly Disposable
- Material: Unifilcon A

LENS PROPERTIES

- Water Content: 43%
- Refractive Index: 1.415
- Oxygen transmissibility(DK) : 60x10⁻¹¹ (cm²/sec) (ml O₂/ml x mmHg) at 35°C
- Polarographic Method (Boundary and Edge Corrected)
- Transmittance: Light Transmittance > 90%
UVA (316-380nm) < 50%
UVB (280-315nm) < 5%

LENS PARAMETERS

- Diameter Range: 14.1 ± 0.2 mm
- Base Curve Range: 8.6 ± 0.2 mm
- Spherical Power Range: +6.00 to -10.00 D

LENS PARAMETERS AVAILABLE

- Chord Diameter: 14.1 mm
- Base Curve: 8.6 mm
- Center Thickness: Minus lens - varies with power (e.g., -3.00D, 0.07mm)
Plus lens - varies with power (e.g., +3.00D, 0.140mm)
- Powers: +6.00 to -10.00 D (0.25 D steps)

●Shelf Life: 5 year

Monthly contact lens passed the fatigue test which means it can bear 500 times of lens remove force rising from thumb and index finger and 600 times of finger rubbing while cleaning the lens.

INSTRUCTION

Be sure read and understand the full contents of IFU (instructions for use, how to insert or remove the lens correctly, as well as the lens care instructions) and discuss it with Eye Care Professional before use.

- Disposal schedule:**
- Daily Disposable Silicone Hydrogel Contact Lens must be replaced every day.
- Monthly Disposable Silicone Hydrogel Contact Lens shall be prescribed for frequent/planned replacement wear with daily removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.
- To insert lenses:**
- a. Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
- b. 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.
- c. Use the fingers of the other hand to lift the upper eyelid.
- d. Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
- e. Look down and slowly remove the hand, releasing the lower lid.
- f. Look straight ahead and slowly remove the other hand, releasing the upper lid, and blink gently.
- g. Use the same technique when inserting the lens for the other eye.
- To remove lenses:**

- a. 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.**
- b. Blink fully several times.
- c. While looking up, slide the lens down onto the white part of the eye.
- d. Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
- e. Remove the other lens by following the same procedure.

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.

- 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 Single Use Daily Wear

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.

For Monthly Use Daily Wear

Always follow the instructions for the lens care products used.

- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling.
- Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- When using hydrogen peroxide lens care systems, the patient must use **ONLY** the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.
- Do not reuse solutions.
- Clean contact lens cases with an appropriate contact lens solution and dry according to lens care instructions. Drying instructions, such as air-drying or wiping with lint-free towel, may vary depending on the lens case used.
- Replace the lens case at regular intervals to help prevent case contamination by microorganisms that can cause eye infection.
- Monthly Disposable Silicone Hydrogel Contact Lens shall be prescribed for frequent/planned replacement wear with daily removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.
- Please use the lens within 30 days after opening of the package.

Non-compliance with replacement of lens schedule and without lens care have been shown to be associated with a higher risk of developing ocular complications.

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.

Care for a Dehydrated Lens

If any Hope-Vision Monthly Disposable Silicone Hydrogel Contact 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.

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.**

It is also very important that whenever any listed contraindication happened such as eye disease, injury, acute inflammation, do not use contact lens.

CONTRAINDICATIONS (REASONS 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 and CAUTIONS

Warnings:

- 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.

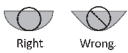
Lens Handling Precautions

- 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.
- 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.

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. 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.

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.

Information about products sold in various countries (if any)

Country	Taiwan	
Model	ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens
Device Registration No	MOHW-MD-No. 006387	MOHW-MD-No. 006872
Marketing date	March 2019	Planning

Intended use which has been registered in other countries (if any)

Country	Taiwan	
Model	ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens
Device Registration No	MOHW-MD-No. 006387	MOHW-MD-No. 006872
Approved date	2019/3/12	2020/7/3
Country	Vietnam	
Model	ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens (Color: Tint Blue, Water content: 43%)	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens (Color: Tint Blue, Water content: 43%)
Device Registration No	220002008/PCBB-BYT	
Approved date	2022/04/14	
Country	Indonesia	
Model	ComCan Puriti Plus Daily Disposable Silicone Hydrogel Contact Lens (Color: Tint Blue, Water content: 43%)	ComCan Puriti Plus Monthly Disposable Silicone Hydrogel Contact Lens (Color: Tint Blue, Water content: 43%)
Device Registration No	AKL 21204220351	AKL 21204220347
Approved date	2022/10/17	2022/10/11

Information about the noticeable safety/operation of medical equipment

This product has not been reported any noticeable safety/operation issue.

REPORTING OF ADVERSE REACTIONS:

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

Manufacturer

Hope-Vision CO., Ltd.
Attn: Product Services No.69, Qunyi Rd., Zhunan Township, Miaoli County, Taiwan (886)37-585-285

www.hope-vision.com

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