Patient information & instructions for use

HOYA Daily Silicone Hydrogel (Spherical, Multifocal, Toric) contact lenses

Contents

- 1. Important information
- 2. Product name and description
- 3. Product properties, parameters and power range
- 4. Intended use
- 5. How the lenses are supplied
- 6. Contraindications
- 7. Warnings
- 8. Precautions
- 9. Adverse reactions
- 10. Wearing schedule for first time wearers
- 11. Directions for use:
 - a. The importance of hygiene
 - b. Removing your lenses from the packaging
 - c. Applying your lenses
 - d. Removing your lenses
 - e. If you experience occasional dryness
 - f. If a lens sticks (stops moving on the eye)
 - g. If a lens decentres on the eye
 - h. If a lens tears in your eyes
- 12. General emergencies
- 13. Reporting adverse reactions
- 14. Abbreviations and symbols on the packaging

1. Important information

Instructions for use - this leaflet contains important product use and safety information. Please read carefully and retain for future reference. Contact lenses should always be prescribed under the guidance of an eye care professional. It is essential that you follow your eye care professional's directions and all labelling instructions for proper use of your contact lenses. It is recommended that you see your eye care professional routinely as directed.

2. Product name and description

HOYA Daily Silicone Hydrogel (sorafilcon A) spherical, toric & multifocal soft contact lenses

HOYA Daily Silicone Hydrogel (sorafilcon A) is a blue tinted 1-day disposable soft silicone hydrogel contact lens, which contains 48% water. Each sterile contact lens is made of 52% silicon-containing methacrylate hydrophilic polymer compound. Reactive UV absorber is used to provide UV absorbing ability. Reactive blue coloured dye (AVBAA) is used to improve handling visibility.

The contact lens is immersed in buffered saline solution within an individual foil-sealed plastic container. 30 contact lenses containers are packed within a multi-pack box. Store at room temperature. Avoid freezing.

3. Product properties, parameters and power range

Lens Properties:

- Refractive Index hydrated: 1.408
- LightTransmittance: ≥ 97%
- Oxygen Permeability (Dk): 112 x 10⁻¹¹ (cm²/sec) (ml O₂ /ml x mm Hg), measured at 35°C (Polarographic method)
- Water Content: 48% by weight in normal saline
- UV Blocking

Product Type	ISO UV Blocking Class	UV-A Luminous Transmittance	UV-B Luminous Transmittance
HOYA Daily Silicone	II	<10%	<2%
Hydrogel (Spherical)			
HOYA Daily Silicone	I	<10%	<1%
Hydrogel (Multifocal)			
HOYA Daily Silicone	Ι	<10%	<1%
Hydrogel (Toric)			

- Base curve: 8.6 mm
- Diameter: 14.2mm for Spherical and Multifocal, 14.5 mm for Toric
- Centre Thickness: Spherical = 0.08mm @ -3.00D (varies with power) Multifocal = 0.09mm @ -3.00D (varies with power) Toric = 0.11mm @ -3.00D Sph/ -0.75D Cylinder (varies with power)

Power range:

	Power Range	ADD power	Cylinder Power	Axes
Spherical	+5.00 to -6.00 (0.25 steps) -6.50 to -12.00D (0.50 steps)			
Multifocal	+5.00 to -6.00 (0.25 steps) -6.50 to -10.00D (0.50 steps)	+1.00 +1.50 +2.00 +2.50		
Toric (for astigmatism)	+5.00 to -6.00 (0.25 steps) -6.50 to -10.00D (0.50 steps)		-0.75 -1.25 -1.75 -2.25	10 / 20 / 90 160 / 170 / 180

Mode of action:

Vision is corrected by the vertex power of the contact lens and the lacrimal fluid between the contact lens and the cornea.

4. Intended use

HOYA Daily Silicone Hydrogel (sorafilcon A) spherical, toric and multifocal soft contact lenses are indicated for the optical correction of refractive ametropia in persons with healthy eyes and should be fitted by an eye care professional

The lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only.

5. How the lenses are supplied

Each lens is packaged in a foil-sealed plastic blister pack, which contains borate buffered solution and is steam sterilized. The package is marked with the base curve, diameter, dioptric power, ADD power (where applicable), manufacturing lot number and expiration date. Lenses are supplied in cartons containing up to 30 individually sealed contact lenses.

6. Contraindications and Restrictions (Reasons Not to Use)

Do not use HOYA Daily Silicone Hydrogel contact lenses when any of the following exists:

- Inflammation or infection of the anterior ocular segment or eyelids
- Reduced corneal sensitivity (corneal hypoesthesia)
- Severe dry eye or lacrimal eye disease
- Any eye disease, injury or abnormality that affects the corneas, conjunctiva or eyelids
- Allergic reactions of the eyes or surrounding tissues that may be induced by contact lens wear or affect contact lens wear

- Systemic diseases that may affect the eye or be exaggerated by contact lens wear. For example, Sjogren's syndrome, rheumatoid arthritis, lupus and collagen vascular diseases affect your ability to wear contact lenses.
- Any corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

7. <u>Warnings (What you should know about contact lens wear)</u>

It is essential that you follow your eye care professional's directions and all labelling instructions.

- HOYA Daily Silicone Hydrogel contact lenses are prescribed for daily wear and are for single use.
- Daily wear or one day contact lenses are not indicated for overnight wear and should not be worn while sleeping. Studies have shown that when daily wear users wear their lenses overnight (outside of intended indication), the risk of eye problems, including ulcerative keratitis is greater than among those who do not wear then overnight¹
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers¹
- Serious eye problems, including corneal ulcers (ulcerative keratitis), can develop rapidly and lead to loss of vision.
- If you experience eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, you should immediately remove the contact lenses and promptly contact your eye care professional. It is recommended that you see your eye care professional regularly as directed.
- 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 the surrounding area. You should continue to use absorbing eyewear as directed.
- Long term exposure to the UV radiation is one of the risk factors associated with cataracts. Exposure is based on several factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.
 - 1. Schein et al. New England Journal of Medicine, September 21,1989;321(12), pp.773-783

8. Precautions

- Ensure your eyes look normal, feel comfortable and your vision is clear.
- Do not use if blister pack is damaged or not completely sealed. This may result in product contamination which can lead to a serious eye infection.
- Once the blister pack is opened the lens must be immediately applied onto the eye. Leaving the lens in the blister packaging after opening may result in microbial contamination and lead to a serious eye infection.

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- Keep a note of the correct lens power for each eye. Before lens insertion, check that the lens power on each foil pack is correct for that eye.
- Insert lenses before applying make-up and remove them before taking off the make-up.
- Always wash and completely dry your hands before handling contact lenses.
- Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
- The lenses are not intended to be cleaned or disinfected and should be discarded after a single use. Reuse can increase the risk of infection or other problems.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- 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.
- Consult your eye care professional before wearing lenses during sporting activities including swimming and water related activities. Exposure to water (or other non-sterile liquids) while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Avoid all harmful or irritating vapours and fumes while wearing contact lenses. If exposed to harmful or irritating vapours, remove and discard the contact lenses
- If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, flush the eyes immediately with fresh saline solution or tap water. Remove and discard the lens and immediately contact your eye care professional or visit a hospital emergency room without delay.
- If you are taking oral contraceptives, consult your eye care practitioner. This is because oral contraceptives may cause a change in the tears and corneal shape and therefore may affect contact lens wear.
- If a contact lens becomes dehydrated or damaged, replace it with a fresh new lens.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not use lenses beyond the expiry date.
- It is recommended that contact lens wearers visit their eye care professional regularly as directed.
- Inform your employer that you wear contact lenses, especially if your job involves using eye protection equipment.

9. Adverse reactions (Possible problems and what to do)

Problems may occur with contact lens wear and may first present as one or more of the following signs and symptoms:

- Foreign body sensation (the feeling of something in the eye)
- Uncomfortable lens
- Eye redness
- Sensitivity to light (photophobia)
- Burning, stinging, itching or excessive watering
- Reduced sharpness of vision
- Rainbows or halos around lights or sensitivity to light (photophobia)
- Increased eye secretions
- Discomfort or pain

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• Severe or persistent dry eyes

If you notice any of the above, you should:

Immediately remove the lens. If the discomfort or the problem stops, then discard the lens and apply a fresh lens new lens on your eye.

If the symptoms continue, you should immediately be seen by your eye care professional so that the problem can be identified and treated to avoid serious eye damage.

10. <u>Wearing schedule for first time wearers (and for those restarting to wear after a longer</u> <u>period of time)</u>

Your eye care professional should determine the appropriate wear schedule based on your eye examination. Build-up of wearing time is important so you must follow your eye care practitioner's directions.

A suggested standard wearing schedule when wearing contact lens for the first time is:

Wearing Day	Wearing Time (hours)
1	6
2	8
3	12
4 to 6	14
≥7	Full day wear (≤ 16)

11.<u>Directions for use</u>

Start each day with a fresh pair of lenses that are discarded at the end of every daily wearing period.

Always check that the lens prescription and parameters as printed on the packaging match your prescription. Do not use if there is a mismatch.

Important hygiene instructions

- Hygiene is one the most important factor in contact lens care and eye health.
- Always wash your hands using mild soap and rinse your hands thoroughly.
- Dry your hands with a clean, lint free towel before handling contact lenses.
- Check that you have the correct lens for each eye.

Removing the lens from the packaging

• Shake the blister pack gently to allow the lens to float in the solution and then peel back the foil.

- Carefully remove the lens from the blister pack by carefully by sliding it up the side of the container. Never use tweezers or other tools. Use your fingertips and be careful to avoid damage with your fingernails. It helps to keep your fingernails short and smooth.
- Inspect the lenses prior to insertion. Insert lenses only if they appear to be clean and Undamaged, free of any nicks and tears.

Checking the lens has not turned inside out

• Ensure the lens is not inside out. Hold the lens on the tip of your index finger and ensure the finger is dry. Hold the lens in front of your eyes and look at the side profile of the lens. If the lens is correctly positioned, it turns slightly in at the edges.

Placing the lens on the eye

- Always start with the same eye
- 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.
- Use the fingers of the other hand to lift the upper eyelid.
- Place the lens directly on the coloured part of the eye (cornea) and gently roll finger away from the lens.
- Look down before slowly releasing the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

Removing the lens

- Always wash your hands using mild soap and rinse your hands thoroughly.
- Dry your hands with a clean, lint free towel before handling contact lenses.
- Blink fully several times.
- While looking up, slide the lens down onto the white part of the eye.
- Remove the lens by pinching gently between the thumb and forefinger.
- If the lens is difficult to grasp, dry your fingers once more and try again.
- Never use tweezers, suction cups, sharp objects or your fingernails to remove lenses from your eyes.

If you experience occasional dryness

Occasional dryness may be relieved by using contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your eye care professional.

If a lens sticks (stops moving on your eye)

If a lens sticks (stops moving), apply a few drops of contact lens rewetting drops or solution approved for use with soft contact lenses, until the lens begins to move freely on the eye. If this problem persists, consult your eye care professional.

If a lens de-centres on your eye

If a lens de-centres on the eye, recentre it by closing your eyelids and gently massaging the lens into place, or with your eyes open gently push the lens in place by applying light finger pressure on the edge of the upper or lower eyelid.

If a lens tears in your eye

If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces are difficult to remove, rinse with saline. If this does not help, contact your eye care professional for assistance.

12. General Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes:

- Flush eyes immediately with fresh saline solution or tap water.
- Remove and discard the lens and immediately contact your eye care professional or visit a hospital emergency room without delay.

13. <u>Reporting of Adverse Reactions</u>

Consult your eye care professional if you experienced any adverse reactions whilst wearing HOYA Daily Silicone Hydrogel (Spherical, Toric &, Multifocal) contact lenses or contact the following:

Manufacturer: HOYA Lamphun Limited 75/2 Moo 4, Tambol Banklang, Amphur Muang, Lamphun 51000 Thailand. Website: <u>hoyavision.com</u>

European Authorized Representative: HOYA Vision Care Radarweg 29-8, 1043 NX Amsterdam, Netherlands. E-mail: <u>contactlens.enquiries@hoya.com</u>



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Abbreviations and symbols on the packaging

ABBREVIATION / SYMBOL	DEFINITION	
BC	Base curve	
DIA	Diameter	
PWR	Power	
D	Dioptre (lens power)	
ADD	Addition power	
L	Left	
R	Right	
(2)	Do not re-use	
LOT	Batch code	
	Use-by date (expiry date)	
	Consult instructions for use	
STERILE	Steam sterilized	
\triangle	Caution	
	Manufacturer	
EC REP	Authorised representative in the EC	
CE	European conformity sign	
UK CA	UK conformity assessed	