

WARNINGS:

Contact lenses are reusable medical devices for single-patient use. They are dispensed by an eye care professional who must inform and train wearers on their use.

Problems associated with wearing contact lenses and using care products can cause serious eye damage. It is therefore essential to follow your healthcare provider's instructions and the information leaflets provided with the contact lenses and care products.

The healthcare professional must inform the wearer of the following wearing instructions:

- Precilens soft lenses are designed to be worn during the day and should not be worn while sleeping.
- After use and prior to reuse, contact lenses must be removed, cleaned, and disinfected with the cleaning products recommended by your eye care professional.
- It is essential to keep all appointments scheduled by your eye care professional, as these are crucial for monitoring and adjusting your lenses.
- Never allow contact lenses to come into contact with tap water.
- Never wear your contact lenses while bathing or showering, or while swimming in a pool or the sea.
- Do not wear contact lenses if there is a risk of exposure to dangerous or irritating fumes.
- If you experience eye pain, excessive tearing, decreased visual acuity, or red eyes, it is essential to remove your contact lenses and contact your eye care professional immediately.

INDICATIONS:

Soft contact lenses are daytime wear lenses, replaced quarterly or annually, for correcting myopia, hyperopia, astigmatism, and presbyopia in regular corneas. Contact lenses are suitable for all types of patients, provided they understand that wearing them is similar to wearing glasses, but that adaptation can sometimes be difficult.

There is no age limit for wearing contact lenses, although it is common to fit young myopic individuals from the age of 10. Lens wear in children requires regular checkups.

BENEFITS AND CLINICAL PERFORMANCE:

Clinical Performance:

Soft contact lenses correct all common refractive errors (myopia, hyperopia, astigmatism, presbyopia). Because soft lenses mould to the central corneal surface, the tear film there is thin and of uniform thickness, thus providing zero power. The specific design of Amyopic lenses, through a power gradient, achieves myopic defocus in the peripheral retina, which controls the progression of the eye's axial length and slows the progression of myopia.

Clinical Benefits:

- Improved visual acuity and field of vision
- Optical correction of regular visual defects (myopia, hyperopia, astigmatism, presbyopia)
- Myopia control with the Amyopic design for progressive myopia in children and young myopic individuals under 20 years of age.

RECOMMENDED REPLACEMENT:

Quarterly or annually, depending on the lenses.

DAILY WEARING TIME:

The daily wearing time for the lenses must be determined by the eye care professional.

During the initial fitting, it is recommended to gradually increase this time. After the adaptation period, the daily wearing time for the lenses can vary from 10 to 15 hours per day.

The list of Precilens soft contact lenses, including claims, possible materials, target population, and recommended replacement schedule, can be accessed by scanning the QR code below:



PACKAGING:

The lenses are packaged in a sterile bottle containing saline solution. The bottle is tamper-evident until first opening. If the packaging is damaged, the lens must not be used.

045 00

Keep out of reach of children.

Update July 2024

PRECILENS - 94000 CRETEIL - France

Precilens

L'INNOVATION VISUELLE SUR MESURE

Precilens Soft Lens Instructions for Use

THIS LEAFLET CONTAINS IMPORTANT INFORMATION THAT EYE CARE PROFESSIONALS SHOULD KNOW AND SHARE WITH WEARERS. PLEASE READ AND KEEP FOR FUTURE REFERENCE.

Other languages can be downloaded from www.precilens.com (QR code below)

Distributors of Precilens lenses are required to print this leaflet in their own language and enclose it with the lenses they ship.














Eye care professionals are also required to give the leaflet to the wearer.

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Description of symbols used on the label:

	Medical device
	Single patient, multiple uses
	Lens name
	Serial number
	UDI (Unique Device Identification) code: unique identification code
	Model number
	European conformity to health and safety requirements and certifying body number
	Use by (sterile expiry date)
	Sterilisation using steam
	Unique sterile barrier system
	Manufacturing date
	Do not use if packaging is damaged
	See leaflet

LENS INSERTION:

Before first use, it is strongly recommended to run a cleaning cycle. Insertion (as well as removal) must be done on a flat, clean, and well-lit surface.

Before each handling, hands must be washed, rinsed, and then dried with a clean, lint-free cloth.

- Never use tweezers or other instruments to remove lenses from the case.
- If you must handle your lenses over a sink, make sure the drainage hole is plugged.
- To avoid confusion between the right and left lenses, it is advisable to always proceed in the same order: for example, the right lens first, then the left lens.
- It is recommended to insert your lenses after your morning routine, before applying makeup, and to remove them before your evening routine and makeup removal.
- Place the lens on your index finger.
- Use the middle fingers of one hand and the other to open your eyelids.
- Place the lens on your eye (Fig. 1). Repeat this procedure for the other eye.

LENS REMOVAL:

- Look up and pull down your lower eyelid with your middle finger.
- Carefully remove the lens from your eye using the tips of your index finger and thumb (Fig. 2).
- Repeat the same procedure for the left lens.



RECOMMENDED CARE PRODUCTS:

A hydrogen peroxide-based solution for daily disinfection, or failing that, a multi-purpose solution for soft lenses.

Enzyme protein-removing tablets can be used once a week in addition to the disinfection solution.

MAINTENANCE:

Warnings:

- Do not change your lens care solutions without consulting your eye care professional.
- **Never use water, saline solution, or comfort drops to clean your lenses.**
- Do not use saliva or any household cleaning products to clean your lenses.
- After the disinfection cycle, discard the solution and do not reuse it.
- Discard any remaining solution in the bottle after the expiration date.
- Change your lens case regularly.

Lens must be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing lenses are necessary to remove deposits that accumulate on their surface. Disinfection is required to destroy germs and bacteria.

- Disinfect your lenses each time you remove them.
- Always use lens care solutions before the expiry date printed on the bottle.
- Keep solutions and lenses away from sources of excessive heat.
- Always follow the instructions on the lens care solution package leaflets.
- When not wearing lenses: store them fully immersed in the appropriate solution. Before reinserting them, a complete cleaning cycle must be performed 24 hours prior to wearing.
- Clean contact lens cases using a disinfecting solution.
- **Never use water to clean the cases.**

RECOMMENDATIONS:

- Your eye care professional has prescribed contact lenses based on the specific characteristics of your eye. Do not change the type or settings of your contact lenses without consulting them.
- Do not wear your contact lenses if they are damaged.
- Keep a pair of glasses with you (in case you need to remove your lenses).
- Do not allow your contact lenses to come into contact with hairspray or other aerosol cosmetic products.
- Wearing contact lenses is not recommended in low-humidity environments (airplanes, hair dryers, etc.).
- Pregnancy and certain medications can disrupt tear production: talk to your eye care professional.

CONTRAINDICATIONS:

DO NOT USE contact lenses in the following cases:

- Acute inflammation or infection of the anterior chamber of the eye.
- Disease, injury, or abnormality affecting the cornea, conjunctiva, or eyelids, except when a prosthetic lens is required.
- Severe tear deficiency (dry eyes).
- Corneal hypoaesthesia (reduced sensitivity of the cornea), if the eyes are not aphakic.
- Systemic disease that may affect the eye or that may be aggravated by wearing contact lenses.
- Allergic reactions of the surfaces or tissues adjacent to the eye that may be induced or aggravated by wearing contact lenses or using related solutions.
- Allergy to an ingredient in a lens care solution.
- Bacterial, fungal, or viral infection of the cornea.
- Red or irritated eyes.

SIDE EFFECTS:

REMOVE THE LENSES IMMEDIATELY if any of the following problems occur:

- Stinging, burning, itching (irritation), or other eye pain
- Loss of comfort compared to initial lens insertion
- Abnormal foreign body sensation in the eye (foreign body, abrasion)
- Excessive tearing
- Red eyes
- Unusual eye discharge
- Decreased visual acuity
- Blurred vision, appearance of rainbows or halos around objects
- Sensitivity to light (photophobia)

If the problem stops once the lens is removed, check the lens:

If the lens is damaged, do not put it back in your eye. Place it in its case and contact your eye care professional.

If the lens is not damaged, clean, rinse, and disinfect it before putting it back in your eye.

If the problem persists after reinserting the lens, remove it immediately and consult your eye care professional to identify the cause of the problem, which may be related to an eye injury (infection, corneal ulcer, neovascularisation, etc.).

DISPOSAL OF THE DEVICE:

Lenses can be disposed of with household waste in accordance with local waste management regulations.

CAUTION:

Any serious incident related to your lenses must be reported to the manufacturer at vigilance@precilens.com and to the relevant health authority in your country.