

WARNINGS:

Contact lenses are reusable medical devices for a single patient.

They are issued by an eye care professional who must inform and train wearers in their use.

Problems associated with contact lens wear and lens care products can cause serious eye damage. It is therefore vital that you follow your practitioner's instructions as well as the instructions on the contact lens and lens care product manual.

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

- The Precilens orthokeratology lenses are designed to be worn with your eyes closed: they should be placed just before going to sleep (in order to avoid wearing them while reading or watching television before going to bed).
- After use and before re-use, the lenses must be taken out, cleaned and decontaminated using the care products recommended by your practitioner.
- Never put lenses in contact with tap water
- It is vital that you attend the scheduled appointments with your practitioner; these are essential to monitor any changes.
- In the event of eye pain, excessive tearing, reduced acuity or red eyes, it is vital that you remove your lenses and contact your practitioner as soon as possible.

For children with night lenses:

- It is essential for parents to ensure perfect hygiene and strict adherence to care and handling instructions to ensure safe wearing.
- If parents cannot ensure that hygiene rules and instructions are followed from time to time (school trips, holidays etc. during which insertion, removal and maintenance of the lenses will no longer be under their control), it is recommended that the child stops wearing the lenses during the period in question, in consultation with your practitioner.

INSTRUCTIONS:

Orthokeratology lenses are corneal lenses to be worn during the night to correct short-sightedness, long-sightedness, astigmatism and presbyopia on regular or irregular corneas.

In all patients, night lenses correct the visual defect during the night thus enabling flawless vision throughout the day.

In children and young people (under 20 years old) with myopia, they can also enable the progress of the myopia to be slowed.

As this technique is reversible, it is necessary to wear your lenses every night to maintain the same quality of vision every day, because when you stop wearing the lenses, the cornea returns to its original shape after 24 to 48 hours and the visual defect reappears.

CLINICAL BENEFITS AND PERFORMANCE:

Clinical performance:

Orthokeratology contact lenses correct all regular visual defects (myopia, hyperopia, astigmatism, presbyopia) by corneal remodelling.

Clinical benefits:

- Improved acuity and visual field
- Optical compensation of regular visual defects (myopia, hyperopia, astigmatism, presbyopia)
- Halted development of myopia in children and young people

RECOMMENDED RENEWAL:

For the safety and efficiency of treatment, it is essential to renew your lenses **every year** in order to avoid an alteration of their geometry.

WEARING TIME:

Reshaping occurs gradually throughout the night. It is recommended to sleep with your lenses in for at least 6 hours for the treatment to be effective.

Precilens orthokeratology lens list including claims, possible materials, the population concerned and recommended renewal can be consulted by scanning the QR code opposite.



PACKAGING:

The lenses are packaged in a mailer containing a decontaminant solution. It is fitted with a tamper-proof system until first opening. If the packaging is damaged, do not use the lens.

**Multifunctional solution for B5 rigid lenses: Active substance Polyhexanide (0.0001%), surfactant Polyhexanide (0.5%), Dexpanthenol (1.0%), lubricating agent HydraFlex-RGP TM (0.5%), isotonic solution of Sodium Chloride (NaCl) without addition of a preservative.*

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Keep out of the reach of children.



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PRECILENS - 25 rue Auguste Perret - 94000 CRETEIL



PRECILENS ORTHOKERATOLOGY LENSES INSTRUCTION MANUAL

**THIS LEAFLET CONTAINS IMPORTANT INFORMATION
THAT THE EYE CARE PROFESSIONAL SHOULD KNOW
AND PASS ON TO THE WEARER.
PLEASE READ IT AND KEEP IT FOR FUTURE USE.**












Other languages can be downloaded from www.precilens.com

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.



Description of symbols used on the label:

	Medical device
	One patient, many uses
	Name of the lens
	Serial number
	UID code: unique identification code
	Model number
 0459	European conformity with health and safety requirements and certifying organisation number
	Use by (expiry date of decontamination solution)
 4°C - 25°C	Storage temperature limit
	Do not use if the packaging is damaged
	Leaflet consultation

PLACING THE LENSES:

It is recommended that you put in your lenses after washing and removing your make-up, just before going to bed.

The lenses should be placed (and removed) over a clean, flat, well-lit surface using a mirror laid flat.

Before handling, hands must be washed, rinsed and dried on a clean, fluff-free towel.

- Never use tweezers or other instruments to remove lenses from the case.
- To avoid any confusion between the right and left lens, it is best to always proceed in the same order: for example, first put the right lens in and then the left one.
- Place the lens on your index finger, fill it with a drop of comfort solution (Fig. 1).
- Lean your head over a mirror placed flat on a table.
- Use your middle fingers to open your eyelids
- Place the lens on the eye (fig. 2). Repeat for the other eye.

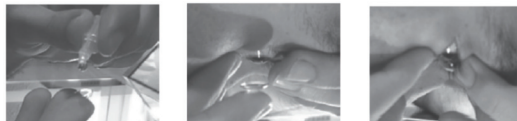
REMOVING THE LENSES:

It is recommended that you remove your lenses before washing and applying make-up in the morning.

20 minutes before removal, instil one drop of preservative-free comfort solution into each eye.

The lenses should be removed (and placed) over a clean, flat, well-lit surface using a mirror laid flat.

- Tilt your head over the mirror.
- With your eyes wide open, place the index finger of one hand on the upper eyelid at the edge of the lashes and the index finger of the other hand on the lower eyelid, at the edge of the lashes.
- Bring your two index fingers together, exerting gentle pressure to release the lens from the eye (fig. 3).



RECOMMENDED CARE PRODUCTS:

- Preservative-free comfort drops or artificial tears for lens insertion and removal.
- A hydrogen peroxide-based solution for daily decontamination.
- Enzymatic deproteinisation tablets to be combined once a week with the decontamination solution.

LENS CARE:

Warnings:

- Do not change lens care solutions without the advice of your practitioner.
- Never use water, saline solution or comfort drops to clean your lenses.

- Do not use your saliva or any household products to clean your lenses.
- After the decontamination cycle, discard the solution and do not reuse it.
- Discard any solution remaining in the bottle after the expiry date has passed.
- Change your case regularly.

Lenses must be cleaned, rinsed and disinfected each time they are removed. Cleaning and rinsing the lenses is necessary to remove deposits from the surface. Disinfection is required to destroy germs and bacteria.

- Decontaminate your lenses every time you remove them.
- Always use lens care solutions before the expiry date indicated on the solution bottle.
- Keep solutions and lenses away from sources of excessive heat.
- Always follow the instructions on the packaging of lens care solutions.
- **When the lenses are not in use:** the lenses should be cleaned, rinsed with sterile solution and dried carefully with a soft, lint-free cloth before being placed in a clean, dry storage case. Before putting them back on, it is necessary to do a complete cleaning cycle 24 hours before wearing.
- Clean contact lens cases using a decontaminating solution.
- Never use water to clean the cases.

RECOMMENDATIONS:

- Never use damaged lenses.
- If you stop wearing the lenses for a week or more, you are advised to make an appointment with your specialist.
- Do not allow your contact lenses to come into contact with lacquer or any other aerosol cosmetic product.
- Wearing lenses is not recommended in very dry atmospheres (airplanes).
- Pregnancy and some medications can cause lachrymal secretion; talk to your practitioner

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 that affects the cornea, conjunctiva or eyelids, except where a prosthetic lens is required.
- Severe deficiency in lachrymal secretions (dry eyes).
- Corneal hypoesthesia (reduced sensitivity of the cornea), if the eyes are non-aphakic.
- A systemic disease that can affect the eye or be aggravated by contact lens wear.
- Allergic reactions of the adjacent surfaces or tissues of the eye which may be induced or aggravated by the wearing of contact lenses or the use of associated solutions.
- Allergy to an ingredient in a lens care solution.
- Bacterial, fungal or viral infection of the cornea.
- Red or irritated eyes.

ADVERSE EFFECTS:

The presence of light halos, which are common at the beginning of orthokeratology lens wear, can persist for up to 3 months. This phenomenon does not prevent the wearing of lenses but makes night driving inadvisable.

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

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

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

If the lens is damaged, it should not be put back into the eye. Place it in the case and contact the practitioner.

If the lens is not damaged, it should be cleaned, rinsed and disinfected before being put back into the eye.

If the problem persists after putting the lens back in, remove it immediately and consult your practitioner to identify the causes of this problem which may be associated with an ocular lesion (infection, corneal ulcer, neovascularisation, etc.).

DISPOSAL OF THE DEVICE:

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

VIGILANCE:

Any serious incident involving your lenses should be reported to the manufacturer at vigilance@preclens.com and to the relevant health authority in your country.