

WARNINGS

Contact lenses are reusable medical devices for a single wearer.

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:

- Precilens rigid lenses are designed for daytime wear and should not be worn while sleeping.
- After use and before re-use, the lenses must be taken out, cleaned and decontaminated using the care products recommended by your practitioner.
- It is vital that you attend the scheduled appointments with your practitioner; these are essential to monitor any changes.
- Never put lenses in contact with tap water.
- Never keep your lenses in while having a bath or shower or while swimming in a pool or in the sea.
- Do not wear lenses if there is a risk of exposure to hazardous or irritating fumes.
- 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.

INSTRUCTIONS:

Hard lenses are corneal lenses for daytime wear to correct short-sightedness, long-sightedness, astigmatism and presbyopia on regular or irregular corneas (keratoconus, corneas that have undergone a keratoplasty or refractive surgery).

In children and young people under 20 years old, PRE AMYOPIC lenses enable the progress of the myopia to be slowed.

CLINICAL BENEFITS AND PERFORMANCE:

Clinical performance:

Rigid contact lenses correct all visual defects, whether regular (myopia, hyperopia, astigmatism, presbyopia) or irregular (keratoconus, trauma, etc.), by maintaining a volume of tears between the lens and the cornea which acts as an optical meniscus and is combined with their dioptric power.

Clinical benefits:

- Improved acuity and visual field
- Optical compensation of regular visual defects (myopia, hyperopia, astigmatism, presbyopia)
- Optical compensation of irregular visual defects (keratoconus, corneal irregularity, trauma, etc.)
- Halted myopia in children and young people with PRE AMYOPIC lenses

RECOMMENDED RENEWAL:

Every 18 months.

Every 12 months for children's and young people's lenses.

DAILY WEARING TIME:

The daily wearing time must be defined by the practitioner.

For the first adjustment, it is recommended to gradually increase this duration.

After the adjustment period, the daily wearing time of the lenses can vary from 10 to 15 hours per day.

The minimum recommended wearing time for PRE AMYOPIC lenses to be effective in reducing myopia is 10 hours per day or more, depending on physiological tolerance.

The Precilens rigid 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 lenses.

**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.*

CE 0459

Keep out of the reach of children.

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PRECILENS - 25 rue Auguste Perret - 94000 CRETEIL - France



PRECILENS RIGID 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
	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 to 25°C	Storage temperature limit
	Do not use if the packaging is damaged
	Leaflet consultation

PLACING THE LENSES:

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

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.
- If you need to handle your lenses over a washbasin, make sure that the plug is in.
- 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.
- We recommend putting your lenses in after your morning wash and before putting make-up on; remove them after removing make-up and cleansing in the evening.
- Place the lens on your index finger.
- Use your middle fingers to open your eyelids
- Place the lens on the eye (figure 1). Repeat for the other eye.

REMOVING THE LENSES:

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

First method

- Lean your head over a mirror placed flat on the table.
- Open your eyes very wide and stare at the mirror, slightly angling your head to the side of the eye concerned.
- Use your right index finger in the corner of your right eyelid and pull down at an angle, forcing yourself to keep your eyes wide open (figure 2)
- The lens will come unstuck and fall onto the mirror.
- Repeat for the left lens.

Second method

- 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. Now bring your two index fingers towards the centre, exerting gentle pressure on the edge of the eyelids to release the lens from the eye (figure 3).



RECOMMENDED CARE PRODUCTS:

- For PRE Perform and PRE Amyopic lenses: a hydrogen peroxide type solution for daily decontamination.
- For other rigid lenses: a multifunctional solution for rigid lenses.

Enzymatic deproteinisation tablets may 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 worn occasionally: the lenses must be stored in the appropriate solution.
- When the lenses are not worn for a long period of time: 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.
- Make sure you have your glasses with you (in case you find yourself obliged to take your lenses out)
- 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 (aeroplane, hairdressers' hair-drying hood, etc.)
- 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

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@precilens.com and to the relevant health authority in your country.