**INDICATIONS**

Hyper-CL™ Therapeutic Soft Contact Lens can provide optical correction during healing, if required, in conjunction with an ophthalmic solution is recommended. Hyper-CL™ Therapeutic Soft Contact Lens increases the therapeutic effect, use of the Hyper-CL™ Therapeutic Soft Contact Lens during the treatment of acute or chronic pathologies, such as corneal edema, to 7 days) to promote corneal healing and relieve corneal pain by protecting the cornea, extending the contact time of the solution.

**PRODUCT DESCRIPTION**

Hyper CL™ Therapeutic Soft Contact Lens is a therapeutic soft contact lens designed to promote corneal healing and relieve corneal pain. In addition, its unique design enables the capture and maintain a drop of solution applied to the contact lens surface. Once applied, the administered drop will migrate into the space between the lens and the cornea, extending the contact time of the solution.

**MATERIAL DESCRIPTION**

Hyper-CL™ Therapeutic Soft Contact Lens consists of 41% Accofilcon A and 59% water by weight when immersed in buffered saline solution. The Hyper-CL™ Therapeutic Soft Contact Lens consists of 41% Accofilcon A and 59% water by weight when immersed in buffered saline solution. The Hyper-CL™ Therapeutic Soft Contact Lens is a therapeutic soft contact lens designed to promote corneal healing and relieve corneal pain. In addition, its unique design enables the capture and maintain a drop of solution applied to the contact lens surface. Once applied, the administered drop will migrate into the space between the lens and the cornea, extending the contact time of the solution.

**Lens Parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>10.0 mm to 17.0 mm</td>
</tr>
<tr>
<td>Base Curve</td>
<td>6.0 mm to 10.0 mm</td>
</tr>
<tr>
<td>Center Thickness</td>
<td>0.1 - 0.5 mm at -3D</td>
</tr>
<tr>
<td>Power</td>
<td>-20D to +20D</td>
</tr>
</tbody>
</table>

**Physical/optical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive Index, Hydrated (35°C)</td>
<td>1.403</td>
</tr>
<tr>
<td>Light Transmittance (@600 nm)</td>
<td>&gt; 94%</td>
</tr>
<tr>
<td>Water Content</td>
<td>59%±2%</td>
</tr>
<tr>
<td>Oxygen Permeability (DK) (35°C)</td>
<td>26 x 10⁻¹ (cm²/sec/mM Hg)</td>
</tr>
<tr>
<td>(ml O2/ml x mm Hg), (revised Fatt method)</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Clear</td>
</tr>
</tbody>
</table>

**CONTRAINDICATIONS**

DO NOT USE the Hyper-CL™ contact lens when any of the following conditions exist:

- Any systemic disease that may affect the eye or worsen by wearing contact lenses.
- Allergic reactions of ocular surfaces or eyelid that may be exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any component of a solution, such as mercury or thimerosal, used to care for the Hyper-CL™ contact lens.
- Patient inability to follow lens care regimen or to obtain assistance to do so.

**WARNINGS**

- Problems with contact lenses and lens care products could result in serious injury to the eye.
- It is essential that patients follow all labeling instructions for proper use of lenses and lens care products, including the lens case. Non-compliance with the manufacturer’s labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Remove the lens(es), and contact your eye care practitioner immediately if you experience any of the following:
  - Excessive tearing
  - Vision changes
  - Pain
  - Loss of vision
  - Eye redness/ irritation
  - Other eye problems
- Erosion can occur due to using of the lenses. In case it occurs the lens should be removed from the eye and you should contact your eye care practitioner immediately.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submerged in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. The patient should ask the eye care practitioner for recommendations about wearing the lenses during any activity involving water.

**PRECAUTIONS**

**Special Precautions for eye care practitioner:**

- Clinical studies have demonstrated that Hyper-CL™ Therapeutic Soft Contact Lenses are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design, material and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient’s ocular health should be carefully weighed against the patient’s need for therapeutic contact lens. The continuing ocular health of the patient and lens performance should be carefully monitored by the prescribing eye care practitioner.
- Pay extra attention when fitting lenses in patients with a post-glaucoma surgery bleb.
- Fluorescein should not be used while the lenses are being worn. The lens can absorb this dye and become discolored. Whenever fluorescein is used in the patient’s eyes, the eyes should be flushed with a sterile saline solution recommended for in-eye use. Wait at least one hour before replacing the lens; if the lens is re-inserted too soon, it can irreversibly absorb residual fluorescein.
- Ensure that the patient is able to promptly remove lenses or has someone else available who can remove the lenses for him or her if needed.
- Instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Erosion could be a rare result of the use of contact lenses. Instruct the patient to remove the contact lenses immediately in case it occurs during the use of Hyper-CL and to contact you.
- Inform the patient to remove the contact lenses immediately after contact with noxious vapour, e.g. chemical or hazardous substances, or a hazardous environment with ocular impact.

**Eye care practitioners should carefully instruct patients about the following precautions for care and safety:**

**Contact lens solutions:**

- Always follow the directions in the contact lens solution package insert.
- To prevent contamination of the lens, only use FRESH, STERILE, lens care solutions. Use of non-sterile solution can lead to severe infection, vision loss or blindness.
- Do not use EXPIRED lens care solutions.
- Various ocular solutions cannot be used together, and not all solutions are safe for use with all lenses.
- Never use solutions recommended for conventional hard contact lenses only.
- When used, sterile, unpreserved solutions should be discarded after the time specified in the labeling directions.
- Do not use saliva or a substance other than the recommended solution for lubricating or wetting lenses.
- Do not store the lenses with water or any non-sterile solution.

**Lens care systems:**

- Only chemical (NOT heat) lens care systems can be utilized for the Hyper-CL™ Therapeutic Soft Contact Lens. Do not alternate or mix lens care systems unless indicated on the solution label.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying will damage the lens.

Follow these directions to care for a dried-out lens:

**Care for a Dried Out (Dehydrated) Lens:**

- Handle the lens carefully. If the lens is adhering to a surface, apply sterile saline before handling.
- Place the lens in the storage case and soak the lens in a recommended rinsing and storing solution for at least one hour, until it softens.
- Before wearing, clean and disinfect the re-hydrated lens, using the recommended lens care system.
• If, after soaking, the lens does not become soft or the surface of the lens remains dry, DO NOT PUT THE LENS IN THE EYE.
• Do not use the re-hydrated lens unless it has been examined by an eye care practitioner.

Handling:
• Always wash, rinse and dry hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely than oil-based cosmetics to damage the lenses.
• Do not touch contact lenses with the fingers or hands if the hands are not free from foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.
• Always handle lenses carefully and avoid dropping them.
• Never use tweezers or other tools to remove lenses from the lens case, unless it is a tool specifically indicated for that use.
• Pour the lens into the hand.
• Do not touch the lenses with fingernails.

LENSES INSERTION:
Insert the lens in the eye as with any other soft contact lens:
• Place the lens on the tip of the index finger; use the other hand to hold the upper eyelid so it won’t blink.
• Pull down the lower eyelid with the other fingers of the applying hand, look up and gently place the lens on the lower part of the eye.
• Slowly release the eyelid and close the eye for a moment, then blink several times until the lens is sitting on the center of the eye.

LENSES FITTING:
A well-fitted lens is one which moves during blinking, centers easily after a blink, bridges the limbus and extends by approximately 1.5 millimeters onto the sclera, moves by no more than 2mm, is comfortable to wear and does not move excessively as a result of blinking or exaggerated eye movements.

NOTE: The Hyper-CL™ Therapeutic Soft Contact Lens does not create a vacuum on the cornea, hence it will move more than a regular soft contact lens. Look at your lens, if the sides are rolled along the edge or folded up, then it is inside out.

WEAR:
The Hyper-CL™ Therapeutic Soft Contact Lens is a short-term wear (7 days) contact lens. The lens can be worn for up to 14 days, with removal after 7 days for cleaning and re-insertion.
• Never wear lenses beyond the period recommended by the eye care practitioner.
• Clean and disinfect the lens using the recommended lens care system.
• If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
• Avoid all harmful or irritating vapors and fumes while wearing lenses.
• The lens should move freely on the eye for the continued health of the eye. If the lens does not move and “sticks” in one place on the eye, follow these directions for Care for a Sticking (Non-moving) Lens: Apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens persists, IMMEDIATELY consult an eye care practitioner.

In case of corneal edema, it is recommended to use a hypertonic solution (NaCl 5%).

Recommended wearing schedule
The Hyper-CL™ Therapeutic Soft Contact Lens is a short-term wear contact lens that can be worn for up to 7 continuous days. The lens should be removed and re-inserted again, after cleansing, for an additional 7 continuous days, for a total of 14 days of wear.
• Always seek professional advice for determining the required period of usage suitable for you.

Recommended antibiotic use
While wearing the Hyper-CL™ Therapeutic Soft Contact Lens for an extended wear, it is recommended to use local antibiotic drops 2-4 times a day, according to the eye care practitioner’s instructions.

Recommended replacement schedule
Hyper-CL™ Therapeutic Soft Contact Lens should be disposed after 14 days.

Lens Case Care:
After removing the lenses from the lens case, empty and rinse the lens case with FRESH, STERILE, lens care solutions. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

• Do not rinse the lens case with water or any other sterile solution.

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing Hyper-CL™ Therapeutic Soft Contact Lenses should be reported to:

Manufacturer:
EyeYon Medical Ltd.
5 Golda Meir St. Ness Ziona, 7403649, Israel
Email: info@eye-yon.com

EUROPEAN UNION AUTHORIZED REPRESENTATIVE (EAR)
MedNet EC-REP GmbH * Borkstrasse 10 * 48163 Muenster * Germany

Label Symbols Definition:

- [Read package insert before use]
- [Use-by date]
- [Sterilized using steam or dry heat]
- [Authorized representative in the European Community]
- [Manufacturer]
- [Do not use if package is damaged]
- [Do not re-sterilize]
- [Caution - For single patient use only]
- [Temperature limit]
- [Catalogue number]
- [Caution: This device should be sold by and used on the order of a physician]
- [Batch code]

Rx Only

0482

LBL0006 Rev. 10.0 Date: June 2020