

**Hyper-CL™ Therapeutic Soft Contact Lens use should be supervised by an eye care practitioner**
**PRODUCT DESCRIPTION**

Hyper-CL™ Therapeutic Soft Contact Lens (Hyper-CL™) is 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**

**Material**  
The Hyper-CL™ consists of 41% Acoficon A and 59% water by weight when immersed in buffered saline solution.

**Lens Parameters**

Diameter (DIA) 10.0 mm to 17.0 mm  
Base Curve (BC) 6.0 mm to 10.0 mm  
Center Thickness 0.1-0.5 mm  
Power (D) -20D to +20D

**Physical/optical properties**

Refractive Index Hydrated (35°C) 1.403  
Light Transmittance (@600 nm) > 94%  
Water Content: 59% ± 2%  
Oxygen Permeability (Dk) (35°C): 26 x 10-11 (cm²/sec) (ml O₂/ml x mm Hg), (revised Fatt method)

**Color:**

Clear

**INDICATIONS**

The Hyper-CL™ Therapeutic Soft Contact Lens is intended for short-term wear (up to 7 days) to promote corneal healing and relieve corneal pain by protecting the cornea during the treatment of acute or chronic pathologies such as corneal edema, corneal erosions, entropion, bullous keratopathy and corneal dystrophies, as well as post-surgical conditions resulting from cataract extraction and corneal surgery. To increase the therapeutic effect, use of the Hyper-CL™ Therapeutic Soft Contact Lens in conjunction with an ophthalmic solution is recommended. Hyper-CL™ Therapeutic Soft Contact Lenses can provide optical correction during healing, if required.

**CONTRAINDICATIONS**

DO NOT use the Hyper-CL™ Therapeutic Soft 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**

• Improper use and/or handling of 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 the use of the lenses. In case it occurs, the lens should be removed from the eye and contact the eye care practitioner immediately.  
 • Do not expose lens to water. 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.  
 • DO NOT use if product appears to be damaged and/or the package has been opened.

**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 an alternative lens is 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 lens 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.  
• Instruct 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.  
• Pay extra attention to debris (trucus and cells) accumulation in contact lens storage solution. For corneal edema treatment, it is recommended to use a hypertonic solution (NaCl 5%).

As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. Provide patient with a recommended follow-up schedule.

• 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 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.

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## USO

La lente de contacto blanda terapéutica Hyper-CL™ es una lente de contacto para uso de corto plazo (7 días). La misma lente puede ser utilizada hasta un total de 14 días, y se retira después de 7 días para su limpieza y re inserción. La duración del tratamiento con Hyper-CL™ para indicaciones agudas y crónicas se determinará por el oftalmólogo. Nunca use lentes más allá del período recomendado por el oftalmólogo.

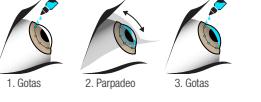
- Limpie y desinfecte la lente utilizando el sistema para el cuidado de lentes recomendado por el oftalmólogo.
- Si se usan productos en aerosol, como aerosol para el cabello, mientras usa lentes, tenga cuidado y mantenga los ojos cerrados hasta que el aerosol se haya asentado.
- Evite todos los vapores y humos nocivos o irritantes mientras usa lentes. Quite las lentes de contacto inmediatamente después del contacto con vapores nocivos, por ej. sustancias químicas o peligrosas, o un entorno peligroso con impacto ocular.
- Pregúntele al oftalmólogo acerca del uso de lentes de contacto durante actividades deportivas.
- Nunca exponga las lentes de contacto al agua.
- Informe a su médico qué usted usa lentes de contacto.
- Comuníquese siempre con el oftalmólogo antes de usar cualquier medicina o medicamento en los ojos.
- Informe siempre al empleador de que usted usa lentes de contacto. Algunos trabajos pueden requerir el uso de equipos de protección ocular o pueden requerir que el paciente no use lentes de contacto.
- Al igual que con cualquier lente de contacto, las visitas de seguimiento son necesarias para asegurar la salud continua de los ojos del paciente. Proporcione al paciente un cronograma recomendable de seguimiento.
- La lente debe moverse libremente sobre el ojo para la salud continua de ésta. Si la lente no se mueve y se "pega" en un lugar del ojo, siga estas instrucciones para el Cuidado de una lente pegada (no se mueve):

  - Aplique unas gotas de la solución de lubricación o rehumectación directamente al ojo y espere hasta que la lente comience a moverse libremente en el ojo antes de retirarla. Si la falta de movimiento de la lente continúa, consulte IMMEDIATAMENTE a su oftalmólogo.

## Instrucciones para uso con gotas:

Aplique gotas según instrucciones, de acuerdo con el protocolo del tratamiento indicado por el oftalmólogo.

Para el tratamiento del edema corneal, se recomienda usar una solución hipertónica (NaCl al 5%).



## Definición de los símbolos de etiqueta:

- Consulte las instrucciones de uso o las instrucciones electrónicas de uso.
- Utilice dentro de la fecha
- Esterilizado al vapor o calor seco
- Sistema de barrera estéril individual.
- Representante autorizado de la comunidad europea / Unión Europea.
- Fabricante
- No utilice si el paquete está dañado y consulte instrucciones de uso.
- No vuelva a esterilizar
- Uso múltiple en un solo paciente.
- Límite de temperatura
- Número de catálogo
- Rx Only
- Código de lote
- Dispositivo médico
- Marca CE de conformidad
- 0482 Número de identificación del organismo notificado

## Cronograma de uso recomendado

La lente de contacto blanda terapéutica Hyper-CL™ es una lente de contacto de uso a corto plazo que se puede usar hasta por 7 días continuos. La lente debe retirarse y puede volver a insertarse, después de la limpieza, durante 7 días continuos adicionales, por un total de 14 días de uso.

• Siempre busque asesoramiento profesional para determinar el período de uso requerido adecuado para usted.

• Advertencia: Si siente irritación o incomodidad, quite las lentes de inmediato y busque asesoramiento profesional.

## Uso recomendado de antibióticos:

Mientras se utilizan las lentes de contacto blandas terapéuticas Hyper-CL™ para un uso prolongado, se recomienda usar gotas de antibiótico local de 2 a 4 veces al día, de acuerdo con las instrucciones del oftalmólogo.

## Cronograma de reemplazo recomendado

La lente de contacto blanda terapéutica Hyper-CL™ se debe desechar después de 14 días.

## Cuidado del estuche de lente:

Después de retirar las lentes de su estuche, vacíe y enjuague el estuche de lentes con una solución, tal como lo recomienda el fabricante de las lentes, y luego permita que se seque al aire. Cuando se vuelve a utilizar el estuche, rellénelo con solución fresca. Reemplace el estuche de lentes de acuerdo con las instrucciones del fabricante o del oftalmólogo.

- Para evitar la contaminación del estuche de lentes, use solo soluciones para cuidado de lentes FRESCAS Y ESTERILES. El uso de una solución no estéril puede provocar una infección grave, pérdida de la visión o ceguera.
- No enjuague el estuche de lentes con agua o con cualquier solución no estéril.

## PRESENTACIÓN DE INFORMES SOBRE REACCIONES ADVERSAS

Todas las experiencias adversas serias y las reacciones adversas observadas en pacientes que usan lentes de contacto blandas terapéuticas Hyper-CL™ deberán ser informadas a:

Fabricante:  
EyeYon Medical Ltd.  
3 Golda Meir St. Ness Ziona, 7403648, Israel  
Correo electrónico: info@eye-yon.com

## REPRESENTANTE AUTORIZADO EN LA UNIÓN EUROPEA (EAR):

MedNet EC-REP Iib GmbH \* Borkstrasse 10 \* 48163 Muenster \* Alemania

## II Hyper-CL™ Instrucciones para el uso

### L'utilizzo delle lenti a contatto morbide per uso terapeutico Hyper-CL™ deve essere supervisionato da un oculista.

#### DESCRIZIONE DEL PRODOTTO

Le lenti a contatto morbide per uso terapeutico Hyper-CL™ (Hyper-CL™) sono progettate per favorire la guarigione della cornea e alleviare il dolore corneale. Il loro particolare design permette inoltre di trattenere e mantenere una goccia di soluzione applicata alla superficie della lente a contatto. Una volta applicata, la goccia somministrata migra nell'interspazio tra la lente e la cornea, prorogando il tempo di contatto della soluzione.

#### DESCRIZIONE DEL MATERIALE

Materiale  
Le Hyper-CL™ consistono per il 41% di Acofilon A e per il 59% di acqua in peso, quando sono immerse nella soluzione salina tamponata.

#### Parametri della lente

Diametro (DIA) da 10,0 a 17,0 mm  
Curva base (CB) da 6,0 a 10,0 mm

Spesore centrale 0,1-0,5 mm

Potere diottrico (D) -2,0D a +2,0D

#### Proprietà fisico/ottiche

Indice di rifrazione idrato (35°C) 1,403  
Trasmisività della luce (@600 nm) > 94%

Aqua contenuta 50%±2%

Permeabilità all'ossigeno (Dk) (35°C): 26 x 10 -11 (cm²/sec) (ml 02/ml x mm Hg)

(método di FATT rivisto)

Trasparente

#### Soluzioni per lenti a contatto:

• Seguire sempre le indicazioni del foglietto illustrativo della soluzione per lenti a contatto.

• Per evitare una contaminazione delle lenti, utilizzare solo soluzioni per la cura delle lenti FRESCHE E STERILI. L'uso di una soluzione non sterile può causare gravi infezioni, perdita della vista o cecità.

• Non usare soluzioni per la cura delle lenti SCADUTE.

• Non è possibile utilizzare contemporaneamente soluzioni oculari diverse e non tutte le soluzioni possono essere usate in sicurezza con tutte le lenti.

• Non usare soluzioni che siano raccomandate unicamente per lenti a contatto idratate convenzionali (RGP).

• Quando utilizzate, le soluzioni sterili non conservate adeguatamente devono essere eliminate dopo la data indicata nelle istruzioni dell'etichetta.

• Non usare la saliva o sostanze diverse dalla soluzione raccomandata per lubrificare o umidificare le lenti.

• Non conservare le lenti in acqua o in altra soluzione non sterile.

Sistemi per la cura delle lenti:

• Per le lenti a contatto morbide per uso terapeutico Hyper-CL™ possono essere utilizzati solo sistemi per la cura delle lenti chimici (NON calore).

• Non alterare o mischiare i sistemi per la cura delle lenti salvo se indicato nell'etichetta della soluzione.

• Quando non indossate, tenere sempre le lenti completamente immerse nella soluzione raccomandata per la conservazione. Se le lenti rimangono a lungo assiccate, possono danneggiarsi.

#### CONTROINDICACIONES

\*NON USE la lente a contatto morbida para uso terapeutico Hyper-CL™ en presencia de una de las siguientes condiciones:

• Qualquier malattia sistémica que pueda involucrar el ojo o peorarla indosando la lente a contatto.

• Reacciones alérgicas de las superficies oculares o de la pálpebra que podrían peorar con el uso de lentes a contatto o de soluciones para lentes a contatto.

• Alerta a uno de los componentes de una solución, ad esempio el mercurio o el thimerosal, utilizada para la cura de lentes a contatto Hyper-CL™.

• Incapacidad del paciente a seguir las instrucciones para la cura de lentes o ad obtener asistencia para farlo.

#### AVERTENCIAS

\*Un'ultraluminazione e/o una manipolazione non corretta delle lenti a contatto o dei prodotti destinati alla loro cura potrebbero causare gravi lesioni all'occhio.

• È fondamentale que i pazienti segnano tutte le istruzioni indicate sull'etichetta per un uso corretto delle lenti e dei relativi prodotti per la cura, incluso l'astuccio portante. Il mancato rispetto delle istruzioni per la cura delle lenti specificate nell'etichetta e fornite dal produttore può esporre il paziente ad un rischio importante de sviluppare una grave infusione oculare.

• I problemi agli occhi, ivi incluse le ulcere corneali, possono svilupparsi rapidamente e portare alla perdita della vista. Rimuovere la lente o le lenti e contattare immediatamente il proprio oculista se si verifica una delle seguenti situazioni:

- Lacrimazione eccessiva
- Modifiche nella vista
- Dolore
- Perdita della vista
- Rossores/ Irritazione dell'occhio
- Altri problemi agli occhi

• L'uso di lentes può causare erosione. Nel caso in cui ciò si verifica, rimuovere la lente dall'occhio e contattare immediatamente il proprio oculista.

• Non esporre le lentes all'acqua. L'acqua può contenere microorganismi que possono causare gravi infezioni, perdita della vista o cecità. Se le lentes sono state immerse nell'acqua durante attività di nuoto in piscina, laghi o ocean,

- il paciente deve smaltrirle e sostituirle con un nuovo paño.
- NON USE il prodotto se sembra danneggiato e/o en el caso en la cual la confezione sia stata abierta.
- No enjuague el estuche de lentes con agua o con cualquier solución no estéril.

#### PRECAUZIONI

##### Precauciones particulares per gli oculisti:

• Studi clinici hanno dimostrato che le lenti a contatto morbide per uso terapeutico Hyper-CL™ sono sicure ed efficaci per l'uso previsto. Tuttavia, gli studi clinici potrebbero non aver indicato tutte le configurazioni di progettazione o i parametri delle lenti attualmente disponibili in questo materiale. Di conseguenza, nel selezionare geometria, materiale e parametri appropriati, l'oculista deve prendere in considerazione tutte le caratteristiche delle lenti che potrebbero influenzare le loro prestazioni e la salute dell'occhio, ivi inclusa la permeabilità all'ossigeno, la bagnabilità, lo spessore centrale e il diametro della zona ottica.

• L'impatto potenziale di questi fattori sulla salute oculare del paziente va attentamente pesato rispetto al bisogno del paziente di lenti a contatto per uso terapeutico. L'oculista prescrittore deve monitorare attentamente e continuamente la salute oculare del paziente e le prestazioni delle lenti.

• Pulire e disinfettare le lenti usando il sistema per la cura delle lenti raccomandato dall'oculista.

• Nel caso in cui si utilizzi prodotti spray, come la lacca per capelli, mentre si indossano le lenti, prestare attenzione e tenere gli occhi chiusi fino a quando lo spray non si sia depositato.

• Evitare tutti i vapori e i fumi nocivi o irritanti mentre si indossano le lenti. Rimuovere immediatamente le lenti a contatto in caso di contatto con vapori nocivi, ad esempio sostanze chimiche o pericolose o con un ambiente pericoloso che possa avere un impatto a livello oculare.

• Prestare attenzione particolare quando si inseriscono le lenti in pazienti che soffrono di bozzo a seguito di chirurgia del glucoma.

• Non utilizzare la fluorescina se il paziente indossa le lenti a contatto per uso terapeutico. L'oculista prescrittore deve monitorare attentamente e continuamente la salute oculare del paziente e le prestazioni delle lenti.

• Per evitare una contaminazione del portante, utilizzare solo soluzioni per la cura delle lenti FRESCHE E STERILI. L'uso di una soluzione non sterile può causare gravi infezioni, perdita della vista o cecità.

• Non sciacquare il portante con acqua o una soluzione non sterile.

#### COMUNICAZIONE DI EFFETTI COLLATERALI NEGATIVI

Tutti gli effetti collaterali negativi gravi e le reazioni avverse osservate in pazienti che indossano le lenti a contatto morbide per uso terapeutico Hyper-CL™ sono segnalate a:

Produttore:  
EyeYon Medical Ltd.  
3 Golda Meir St. Ness Ziona, 7403648, Israele  
Email: info@eye-yon.com

#### INSTRUCCIONES PARA EL USO

### A utilização das Lentes de Contato Gelatinosas para Uso Terapêutico Hyper-CL™ deve ser supervisionada por um oftalmologista

#### DESCRIÇÃO DO PRODUTO

As Lentes de Contato Gelatinosas para Uso Terapêutico Hyper-CTM (Hyper-CL™) foram criadas para ajudar na cicatrização da córnea e aliviar a dor da córnea. Além disso, seu design exclusivo permite a captura e manutenção de uma gota de solução aplicada na superfície da lente de contato. Uma vez aplicada, a gota administrada migra para o espaço entre a lente e a córnea, prorrogando o tempo de contato da solução.

#### Instruções para o uso:

Aplicar a goccia come indicato nel protocolo di trattamento ricevuto dall'oculista.

Per il trattamento dell'edema corneale, si raccomanda di utilizzare una soluzione ipertonica (NaCl 5%).

#### DEFINIÇÃO DO MATERIAL

Material  
As lentes Hyper-CL™ consistem em 41% de Acofilon A e 59% de água em peso quando imersas na solução salina tamponada.

#### Parâmetros da lente

Diametro (DIA) 10,0 mm a 17,0 mm

Curva de base (CB) 6,0 mm a 10,0 mm

Espessura central 0,1-0,5 mm

Dioptrias (D) -2,0D a +2,0D

#### Propriedades físicas/ópticas

Índice de refração hidratadas (35°C): 1,403

Transmissância da luce (@600 nm): > 94%

Teor de água: 50%±2%

Permeabilidade ao oxigénio (Dk) (35°C): 26 x 10 -11 (cm²/sec) (ml 02/ml x mm Hg)

(método Fatt revisado)

Cor: Incolor

#### INDICAÇÕES

A Lente de Contato Gelatinosa para Uso Terapêutico Hyper-CL™ destina-se a:

a utilização a curto prazo (até 7 dias) para promover a cicatrização da córnea e aliviar as dores na córnea, protegendo a córnea durante o tratamento de patologias agudas ou crônicas, como edema da córnea, erosões da córnea, entropio, ceratopatia bolhosa e distrofias da cór