



VISCODERM® HYDROBOOSTER Product Specifications

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VISCODERM[®] hydrobooster



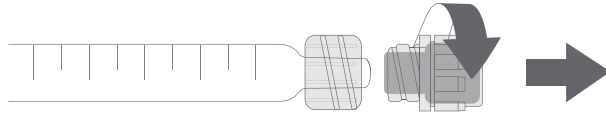
hydroACTION ●●●●●
liftACTION ●●○○○
CROSS-LINKING ■□□□□



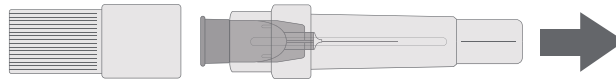
- IT** ACIDO IALURONICO RETICOLATO
PARTICOLARMENTE INDICATO PER AREE DINAMICHE
DEL VOLTO.
- EN** CROSS-LINKED HYALURONIC ACID
PARTICULARLY INDICATED FOR DYNAMIC AREAS
OF THE FACE.
- FR** ACIDE HYALURONIQUE RÉTICULÉ
PARTICULIÈREMENT INDIQUÉ POUR LES RÉGIONS
DYNAMIQUES DU VISAGE.
- ES** ÁCIDO HIALURÓNICO RETICULADO
INDICADO ESPECIALMENTE PARA ÁREAS DINÁMICAS
DEL ROSTRO.



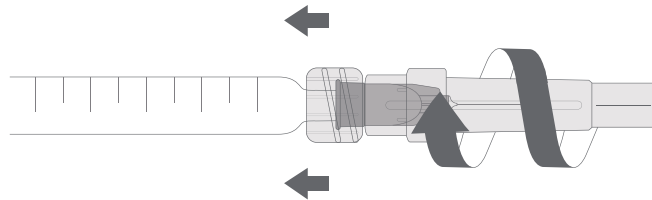
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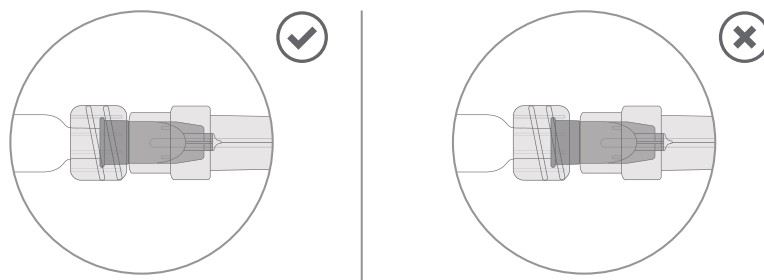
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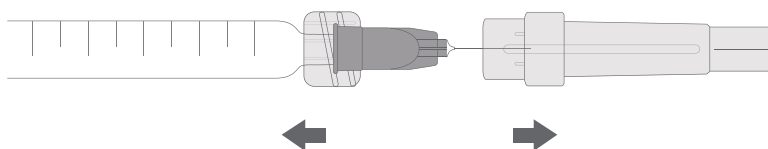
3



4



5



IT

ASSEMBLAGGIO DELL'AGO SULLA SIRINGA

Per una manipolazione ottimale dei prodotti **VISCODERM®** hydrobooster è importante assemblare l'ago sulla siringa seguendo i 5 passaggi illustrati nello schema (Figure da 1 a 5).

1

Reggere saldamente la siringa di vetro e il luer-lock tra il pollice e l'indice. Afferrare il cappuccio di protezione e svitarlo.

2

Rimuovere il cappuccio dell'ago e inserire saldamente la filettatura dell'ago sull'estremità della siringa.

3

Avvitare delicatamente l'ago in senso orario. Continuare ad avvitare finché la filettatura entra a contatto con il corpo della siringa.

4

Verificare che l'ago sia inserito correttamente nella filettatura. Il mancato rispetto di queste precauzioni potrebbe causare il rischio di distacco dell'ago e/o di fuoriuscite dal luer-lock.

5

Con la siringa in una mano e il cappuccio nell'altra, rimuovere la protezione dell'ago tirando in modo deciso.

EN

ASSEMBLING THE NEEDLE ON THE SYRINGE

For optimal handling of **VISCODERM®** hydrobooster products, it is important to assemble the needle on the syringe in accordance with the 5 steps shown in the diagram (see figures 1 to 5).

1

Firmly hold the glass syringe and the luer-lock between the thumb and the index fingers. Grasp the protective cap and unscrew it.

2

Remove needle cap, then firmly insert the needle thread on the end of the syringe.

3

Gently screw the needle in a clockwise direction. Continue to screw until the thread comes into contact with the body of the syringe.

4

Check that the needle is correctly fitted onto the thread. Failure to follow these precautions could lead to risks of the needle dropping out and/or leaks from the luer-lock.

5

With the syringe held in one hand and the cap in the other, remove the needle protective device by pulling firmly.

FR

ASSEMBLAGE DE L'AIGUILLE SUR LA SERINGUE

Pour une manipulation optimale des produits **VISCODERM®** hydrobooster, il est important d'assembler l'aiguille sur la seringue en suivant les 5 étapes illustrées sur le schéma (Figures 1 à 5).

1

Tenir fermement la seringue en verre et le luer-lock entre le pouce et l'index. Saisir l'embout protecteur et le dévisser.

2

Ôter l'embout de l'aiguille et introduire fermement la partie filetée de l'aiguille dans l'extrémité de la seringue.

3

Visser délicatement l'aiguille dans le sens des aiguilles d'une montre. Continuer à visser jusqu'à ce que le filetage entre en contact avec le corps de la seringue.

4

Vérifier que l'aiguille est bien insérée dans le filetage. Le non-respect de ces instructions peut entraîner le risque de sortie de l'aiguille et / ou de fuites par le luer-lock.

5

En tenant la seringue d'une main et l'embout de l'autre, retirer la protection de l'aiguille en tirant d'un coup sec.

ES

MONTAJE DE LA AGUJA EN LA JERINGA

Para una manipulación óptima de los productos **VISCODERM®** hydrobooster es importante montar la aguja en la jeringa siguiendo los 5 pasos mostrados en el esquema (Figuras 1 a 5).

1

Sujetar firmemente la jeringa de vidrio y el Luer-Lock entre el pulgar y el índice. Agarrar el capuchón de protección y desenroscarlo.

2

Retirar el capuchón de la aguja e introducir firmemente la parte roscada de la aguja en el extremo de la jeringa.

3

Enroscar con cuidado la aguja en el sentido de las agujas del reloj. Seguir enroscando hasta que la parte roscada entre en contacto con el cuerpo de la jeringa.

4

Comprobar que la aguja se haya introducido correctamente en la parte roscada. El incumplimiento de estas instrucciones puede provocar riesgo de desprendimiento de la aguja y/o de fugas desde el Luer-Lock.

5

Con la jeringa en una mano y el capuchón en la otra, retirar la protección de la aguja tirando firmemente.

TO BE SOLD WITH MEDICAL PRESCRIPTION ONLY. The product is intended for use by authorized medical practitioners only. Do not use for indications different from those described in this instruction leaflet.

DESCRIPTION

VISCODERM® hydrobooster is a re-absorbable medical device (sterile, pyrogen-free and physiological gel) used to restore intradermal hydration and to help improve the structure and elasticity of the skin. The main ingredient is cross-linked hyaluronic acid, which is not of animal origin, produced by bacterial fermentation.

COMPOSITION

Cross-linked hyaluronic acid.....	25 mg/g
Phosphate buffer, water for injectable solutions.....	1.1 g

PACK

VISCODERM® hydrobooster is available in a 1.1 ml pack. Each pack contains:

- instruction leaflet
- sealed blister containing one 1.1 ml pre-filled, single use/disposable syringe and 2 adhesive product traceability labels to be applied to the patient's record;
- 2 sterile Terumo needles 29G X 1/2" C€ 0197;

METHOD OF USE

VISCODERM® hydrobooster should be injected in the dermis with the aim of restoring intracutaneous hydration and contributing to improvement of the structure and elasticity of the skin. The supplementation of the extracellular matrix helps create a physiological environment conducive to cell vitality. The presence of hyaluronic acid with a low-percentage of cross-linking ensures that the effects are maintained for prolonged periods of time.

INTENDED USE

VISCODERM® hydrobooster is an injectable medical device for restoring intradermal hydration and to help improve the structure and elasticity of the skin.

VISCODERM® hydrobooster is a skinbooster which, thanks to its rheological properties and viscosity, is specifically indicated for dynamic areas of the face, such as the perioral and periocular zones.

The treatment results depend on the skin type and the nature of the imperfections.

INSTRUCTIONS FOR USE

Prior to each treatment with **VISCODERM®** hydrobooster, the medical practitioner must perform an adequate anamnesis and an overall assessment of the patient's condition, in order to ensure absolute absence of contra-indications to the implant.

Local anaesthetic may be used for treatment of the perioral area, with the purpose of ensuring the patient's comfort.

Before treatment the medical practitioner must explain the procedure to the patient including its nature, warnings, precautions, possible individual results, potential adverse reactions, the expected duration of the implant and the eventual possibility of a follow-up treatment for maintaining and/or refining the obtained results.

Before proceeding with the implant, the treated area must be cleaned with an antiseptic solution which does not contain chlorhexidine and quaternary ammonium salts.

Remove the syringe from the blister, unscrew the needle base and screw the needle onto the syringe's luer-lock connection. Remove the protective needle cover only when ready to perform the treatment.

VISCODERM® hydrobooster is administered with the sterile needles, having standardized connections in compliance with Luer-Lock requirements, included in the package.

The implant should be injected in the dermis; the procedure is however at the medical practitioner's discretion and depends on the correction to be performed and the injection technique applied.

After the treatment it is advisable to gently massage the treated area.

DOSAGE AND ADMINISTRATION

The volumetric markings printed on the syringe are indicative: the medical practitioner will determine the dosage to be used for each individual case.

The number of treatments depends on various factors regarding the physiology of the patient (skin type, individual metabolism, anatomy, age), lifestyle and the injection techniques used. The recommended treatment protocol includes 2 sessions with a 2 month interval. To prolong the obtained results it is recommended to repeat the treatment protocol twice a year.

PRECAUTIONS

During the treatment, follow the precautions normally taken in cases of percutaneous procedures. The risks are those commonly connected with infection in relation to the type of treatment. **VISCODERM®** hydrobooster must not be used on patients affected by:

- infectious or inflammatory processes in the vicinity of the area to be treated
- known hypersensitivity to Keloids
- allergy to components
- immune system disorders
- chronic pathological conditions of the skin
- disorders due to coagulation factors or in the case of ongoing anti-coagulant therapies

Around the time of the treatment, the patient should avoid taking substances (aspirin, NSAIDs, Vit. E) which affect blood fluidity, in order to minimize the possibility of bruising or bleeding of the treated areas.

Injection of **VISCODERM®** hydrobooster is absolutely prohibited in implants including tendon, bone, muscle and breast.

Following treatment, and up to complete absorption of swelling and redness, the implanted areas should not be exposed to excessive heat (sun, UV tanning sessions, lasers), nor to intense cold.

Following use, dispose of needles and syringes following the procedures for hospital waste.

ADVERSE REACTIONS, WARNINGS AND CONTRAINDICATIONS

Commonly in cases of percutaneous injection, certain reactions may occur:

- inflammatory reactions (reddening, oedemas, etc.) sometimes associated with itching and sensitive to touch
- haematoma
- hardening or nodules at the point of injection
- colouring and discolouring of the skin at the point of injection

These usually disappear after a few days. If the symptoms persist beyond a week the patient should refer promptly to her or his medical practitioner.

VISCODERM® hydrobooster is to be used intracutaneously and must not be injected into blood vessels.

No overdose phenomena or interactions with pharmaceutical drugs are known.

Do not use if pregnant.

VISCODERM® hydrobooster is available in sterile single-use packs.

It is prohibited to re-use the contents for subsequent treatments or for different patients. Once opened the product should be used immediately.

Unused product must be disposed of.

Do not use the product if the package is open or damaged.

Do not mix with other injectable substances, nor use other implants in conjunction with **VISCODERM®** hydrobooster.

The treatment should be performed in an aseptic environment, using the appropriate techniques. Fill out the adhesive traceability label present in the package and apply it to the patient's record kept in the medical practitioner's office.

Keep away from children.

STORAGE CONDITIONS

VISCODERM® hydrobooster must be stored between 2°C and 28°C.

Do not freeze Do not expose to heat sources.

SOLO ESTÁ PERMITIDA LA VENTA CON PRESCRIPCIÓN MÉDICA. Este producto está previsto para ser utilizado únicamente por médicos autorizados. No utilizar para fines distintos de los indicados en este folleto de instrucciones.

DESCRIPCIÓN

VISCODERM® hydrobooster es un dispositivo médico reabsorbible (gel estéril, libre de pirógenos y fisiológico) utilizado para restaurar la hidratación intradérmica y para ayudar a mejorar la estructura y elasticidad de la piel. El ingrediente principal es el ácido hialurónico reticulado, que no es de origen animal, producido por fermentación bacteriana.

COMPOSICIÓN

Ácido hialurónico reticulado.....25 mg/g
Tampón fosfato, agua para soluciones inyectables.....1,1 g

ENVASE

VISCODERM® hydrobooster está disponible en una caja de 1,1 ml. Cada caja contiene:

- folleto de instrucciones;
- 1 blíster sellado que contiene una jeringa de un solo uso/desechable precargada con 1,1 ml y 2 etiquetas adhesivas de trazabilidad del producto para colocar en el expediente del paciente;
- 2 agujas Terumo estériles 29G X 1/2" C€ 0197.

MÉTODO DE USO

VISCODERM® hydrobooster debe inyectarse en la dermis con el objetivo de restaurar la hidratación intracutánea y contribuir a la mejora de la estructura y elasticidad de la piel. La suplementación de la matriz extracelular ayuda a crear un entorno fisiológico propicio para la vitalidad celular. La presencia de ácido hialurónico con un bajo porcentaje de reticulación asegura que los efectos se mantengan durante períodos de tiempo prolongados.

USO PREVISTO

VISCODERM® hydrobooster es un dispositivo médico inyectable para restaurar la hidratación intradérmica y para ayudar a mejorar la estructura y elasticidad de la piel.

VISCODERM® hydrobooster es un skinbooster que, gracias a sus propiedades reológicas y viscosidad, está específicamente indicado para zonas dinámicas del rostro, como las zonas perioral y periocular.

Los resultados del tratamiento dependen del tipo de piel y de la naturaleza de las imperfecciones.

INSTRUCCIONES DE USO

Antes de cada tratamiento con **VISCODERM® hydrobooster**, el médico debe realizar una anamnesis adecuada y una evaluación general del estado del paciente, con el fin de garantizar la ausencia absoluta de contraindicaciones para el implante.

Anestesia local puede ser utilizada para el tratamiento de la zona perioral, con el propósito de asegurar la comodidad del paciente.

Previo al tratamiento, el médico debe explicar el procedimiento al paciente, incluyendo su naturaleza, advertencias, precauciones, posibles resultados individuales, posibles reacciones adversas, la duración esperada del implante y la eventual posibilidad de un tratamiento de seguimiento para mantener y/o refinar los resultados obtenidos.

Antes de proceder con el implante, el área tratada debe limpiarse con una solución antiséptica que no contenga clorhexidina o sales de amonio cuaternario.

Retirar la jeringa del blíster, desenroscar la base de la aguja y enroscar la aguja en la conexión Luer-Lock de la jeringa. Retirar la cubierta protectora de la aguja solo cuando esté listo para realizar el tratamiento.

VISCODERM® hydrobooster se administra con las agujas estériles, que tienen conexiones estandarizadas de acuerdo con los requisitos Luer-Lock, incluidas en el paquete.

El implante debe inyectarse en la dermis; sin embargo el procedimiento es a discreción del médico y depende de la corrección que se vaya a realizar y de la técnica de inyección aplicada.

Después del tratamiento es aconsejable masajear suavemente la zona tratada.

DOSIFICACIÓN Y ADMINISTRACIÓN

Las marcas volumétricas impresas en la jeringa son indicativas: el médico determinará la dosis que se utilizará para cada caso individual.

El número de tratamientos depende de varios factores relacionados con la fisiología del paciente (tipo de piel, metabolismo individual, anatomía, edad), estilo de vida y las técnicas de inyección utilizadas. El protocolo de tratamiento recomendado incluye 2 sesiones con un intervalo de 2 meses. Para prolongar los resultados obtenidos se recomienda repetir el protocolo de tratamiento dos veces al año.

PRECAUCIONES

Durante el tratamiento, adoptar las precauciones habituales que se toman en los procedimientos percutáneos. Los riesgos son los comúnmente relacionados con infección en relación con el tipo de tratamiento. **VISCODERM®**

hydrobooster no debe utilizarse en pacientes afectados por:

- procesos infecciosos o inflamatorios próximos a la zona que se va a tratar;
- hipersensibilidad conocida a los queloides;
- alergia a los componentes;
- trastornos del sistema inmunitario;
- condiciones patológicas crónicas de la piel;
- trastornos debidos a factores de coagulación o en caso de terapias anticoagulantes en curso.

Durante el tiempo de tratamiento, el paciente debe evitar tomar sustancias (aspirina, AINE, vitamina E) que afecten a la fluidez de la sangre, con el fin de minimizar la posibilidad de hematomas o sangrado de las zonas tratadas.

La inyección de **VISCODERM®** hydrobooster está totalmente prohibida en implantes que incluyan tendones, huesos, músculos o senos.

Después del tratamiento y hasta la completa absorción de la hinchazón y el enrojecimiento, las zonas implantadas no deben exponerse a calor excesivo (sol, sesiones de bronceado UV, láseres), ni a frío intenso.

Después del uso, desechar las agujas y las jeringas siguiendo los procedimientos para residuos hospitalarios.

REACCIONES ADVERSAS, ADVERTENCIAS Y CONTRAINDICACIONES

Comúnmente en casos de inyección percutánea pueden ocurrir ciertas reacciones:

- reacciones inflamatorias (enrojecimiento, edemas, etc.) a veces asociadas con picazón y sensibles al tacto;
- hematomas;
- endurecimiento o nódulos en el punto de inyección;
- coloración y decoloración de la piel en el punto de inyección.

Estos suelen desaparecer después de unos días. Si los síntomas persisten por más de una semana, el paciente deberá consultar de inmediato a su médico.

VISCODERM® hydrobooster se debe utilizar por vía intracutánea y no debe inyectarse en los vasos sanguíneos.

No se conocen fenómenos de sobredosis o interacciones con fármacos.

No usar en caso de embarazo.

VISCODERM® hydrobooster está disponible en cajas estériles de un solo uso.

Está prohibido reutilizar el contenido para tratamientos posteriores o para diferentes pacientes. Una vez abierto, el producto debe utilizarse de inmediato.

El producto no usado debe ser desechado.

No utilizar el producto si el embalaje está abierto o dañado.

No mezclar con otras sustancias inyectables, ni utilizar otros implantes junto con **VISCODERM®** hydrobooster.

El tratamiento debe realizarse en un entorno aséptico, utilizando las técnicas apropiadas. Completar la etiqueta adhesiva de trazabilidad presente en la caja y colocarla en el expediente del paciente que se guarda en la oficina del médico. Mantener alejado de los niños.

CONDICIONES DE ALMACENAMIENTO

VISCODERM® hydrobooster debe almacenarse a una temperatura entre 2 °C y 28 °C.

No congelar. No exponer a fuentes de calor.



- Sterilizzato al calore umido
- Sterilized using steam
- Stérilisé à la vapeur
- Esterilización por vapor
- Dampfsterilisiert
- Otoklav ile sterilize edilmıştır
- Стерилизовано паром

• تم تعقيمه باستخدام البخار



- Vedere le istruzioni per l'uso
- Consult instruction for use
- Consulter les précautions d'emploi
- Consultar las instrucciones de uso
- Gebrauchsanweisung beachten
- Kullanma kılavuzuna bakınız
- Следовать инструкциям по применению

• اتباع ارشادات الاستعمال



- Attenzione, leggere le istruzioni per l'uso
- Attention, see instruction for use
- Attention, lire les instructions d'utilisation
- Precaución, leer las instrucciones para el uso
- Achtung, die Gebrauchsanleitung lesen
- Dikkat! Kullanım kılavuzunu okuyunuz
- Внимание, прочесть инструкции по эксплуатации

• انتبه، يجب قراءة التعليمات قبل الاستخدام



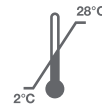
- Non disperdere nell'ambiente
- Keep clean the environment
- Ne pas disperser le produit dans la nature
- No dispersar en el ambiente
- Vorschriften zur Entsorgung beachten
- Bulunduğunuz ortama yaymayınız
- Не оставлять в окружающей среде

• لا تتخلص من المنتج في البيئة



- Conservare al riparo dalla luce
- Store away from light
- Ne pas exposer le produit à la lumière
- Conservar lejos de fuentes de luz
- Vor Licht geschützt aufbewahren
- Direkt ısı kaynaklarından uzak tutunuz
- Хранить в тёмном месте

• يحفظ بعيداً عن النور



- Conservare tra 2°C e 28°C
- Store between 2°C / 28°C
- Conserver entre 2°C et 28°C
- Conservar entre 2°C y 28°C
- Zwischen 2 und 28 °C aufbewahren
- 2° ile 28° C arasında muhafaza ediniz
- Хранить при температуре от 2°C до 28°C

• يحفظ بين 2 °م و 28 °م



LOT

- Monouso
- Do not re-use
- Ne pas réutiliser
- No reutilizar
- Nicht wiederverwenden
- Tek Kullanımlıktır
- Не подлежит повторному использованию

• يستخدم لمرة واحدة فقط

- Lotto
- Batch Code
- Code lot
- Número de lote
- Chargenbezeichnung
- Lot no
- Код партии

• رقم التشغيل



- Utilizzare entro il...
- Use-by date
- Date de péremption
- Fecha límite de utilización
- Verwendbar bis
- Son kullanma tarihi
- Использовать до истечения срока годности

• يستعمل قبل تاريخ

- Fabbricante
- Manufacturer
- Fabricant
- Fabricante
- Hersteller
- Üretici
- Изготовитель

• الشركة المصنعة

STERILE EO

- Sterilizzato con ossido di etilene
- Sterilized using ethylene oxide
- Stérilisé par oxyde d'éthylène
- Esterilización por óxido de etileno
- Mit Ethylenoxid sterilisiert
- Sterilized with ethylene oxide
- Стерилизовано этиленоксидом

• معقم بأوكسيد الإيثيلين

VISCODERM[®]

hydrobooster



Ago - Needle - Aiguille - Aguja - Nadel - Iğne - Игла - إبرة

29G X 1/2"



STERILE EO



TERUMO Europe N.V.
Interleuvenlaan 40
3001 Leuven - Belgium

Distribuito da / Distributed by
IBSA Farmaceutici Italia Srl
Via Martiri di Cefalonia, 2
26900 Lodi - Italy
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fax +39.0371.617244
www.ibsaderma.com



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Via San Gottardo, 10
6900 Lugano - Switzerland



Rev.2 del 03/2019



VISCODERM
SKINKÒ

VISCODERM
SKINKÒ E



Viscoderm Skinkò - Hyaluronic Acid 2 mg + Antiaging Complex

Viscoderm Skinkò E - Hyaluronic Acid 32 mg + Antiaging Complex

FORM and PACKAGING

Clear, colorless, injectable sterile solution for single use, presented in a case of 10 x 5ml vials.

COMPOSITION

For one 5ml vial:

Non-reticulated Hyaluronic Acid of biotechnological origin.

Buffered medium containing: Ammonium Molybdate, Ammonium Metavanadate, Calcium Chloride, Iron Sulfate, Potassium Chloride, Copper Sulfate, Magnesium Chloride, Manganese Sulfate, Sodium Acetate, Sodium Hydrogen Carbonate, Sodium Chloride, Sodium Hydrogen Phosphate, Sodium Metasilicate, Sodium Selenite, Nickel Chloride, Tin Chloride, Zinc Sulfate, Alanine, Arginine, Asparagine, Aspartic Acid, Cysteine, Glutamine, Glutamic Acid, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Proline, Serine, Threonine, Tryptophan, Tyrosine, Valine, Adenine (Vit. B4), Biotin (Vit. B8), Calcium Pantothenate (Vit. B5), Choline Chloride, Folic Acid (Vit. B9), Inositol (Vit. B7), Nicotinamide (Vit. B3), Pyridoxine (Vit. B6), Riboflavin (Vit. B2), Thiamine (Vit. B1), Vitamin B12, Deoxythymidine, Glucose, Putrescine, Sodium Pyruvate, Lipoic Acid.

INDICATIONS

The choice between Viscoderm Skinkò (Hyaluronic Acid 2 mg) and Viscoderm Skinkò E (Hyaluronic Acid 32 mg) is left to the practitioner.

Viscoderm Skinkò and Viscoderm Skinkò E are reabsorbable injectable implants for use in the superficial and middle dermis of healthy patients:

- Viscoderm Skinkò: to help reduce the appearance of fine lines and improve hydration of facial epidermis.
- Viscoderm Skinkò E: to help reduce the appearance of wrinkles and fine lines, particularly in the periorbital and perioral areas, slightly increase cheek volume and improve hydration of facial epidermis.

CONTRA-INDICATIONS

- Do not inject into blood vessels.
- Do not use in:
 - patients with hypersensitivity or a known allergy to one of the ingredients.
 - patients with a skin disease or skin damage of any type.
 - patients with a history of autoimmune diseases or undergoing immunotherapy.
 - pregnant or lactating women.
 - individuals under 18 years of age.

PRECAUTIONS FOR USE

- Apply only to healthy skin.
- There is no clinical data available regarding the tolerance of an injection of Viscoderm Skinkò

and Viscoderm Skinkò E into an area that has already been treated with another so-called “permanent” filling product.

One must proceed with caution, even if Viscoderm Skinkò and Viscoderm Skinkò E are not injected at the same level.

- Patients with a history of streptococcic diseases (recurrent tonsillitis, rheumatic fever etc.) must undergo a double test before any implantation. In the case of rheumatic fever with heart involvement, it is recommended not to proceed with the implantation.
- Patients receiving anti-coagulant treatment must be informed of the increased risk of hematomas and bleeding during implantation. For the same reasons, it is recommended to avoid taking a high dose of aspirin during the week preceding implantation.
- Recommend to the patient not to apply makeup for 12 hours following implantation and to avoid prolonged exposure to the sun, UV rays, frost, as well as going into a sauna or hammam, for two weeks following implantation.
- Do not mix with other products.

INCOMPATIBILITIES

There is known incompatibility between Hyaluronic Acid and quarternary Ammonium salts such as Benzalkonium Chloride. Viscoderm Skinkò and Viscoderm Skinkò E should therefore never be placed into contact with these products, or with any medical-surgical equipment treated with this type of product.

UNDESIRABLE EFFECTS

The practitioner must inform the patient that there are potential side effects related to the implantation of this product, such as:

- pain which can be reduced by applying a local anesthetic.
- stinging, redness or slight local inflammation which should disappear after 24 to 48 hours.
- mild edema and small hematomas may develop, but should disappear within 48 hours.

Any other undesirable effect must be reported by the patient to the practitioner as rapidly as possible. The practitioner must remedy it with appropriate treatment. Any other undesirable side effect connected with Viscoderm Skinkò and Viscoderm Skinkò E must be reported to the distributor and/or manufacturer.

INSTRUCTIONS FOR USE

These implants are intended for use by properly qualified practitioners. Before implantation, the practitioner must inform the healthy patient that there are contraindications, incompatibilities and undesirable effects. Implantation is performed in the middle dermis or superficial dermis of the face or neck.

Products	Directions for use
Viscoderm Skinkò	Nappage, papules, point-by-point, transdermal systems
Viscoderm Skinkò E	Point-by-point, retroracing, fan injection technique, cross-hatching technique, transdermal systems

The decision of the use and choice between Viscoderm Skinkò and Viscoderm Skinkò E is left to the practitioner.

Viscoderm Skinkò and Viscoderm Skinkò E must be implanted aseptically, using single-use sterile equipment which is not supplied by the manufacturer. All asepsis and hygiene precautions must be taken to prepare the site, equipment and patient before implantation.

WARNING

Before use:

- check the use-by date on vial labels.
- check that vial is undamaged.
- check the appearance of the solution.

Use at ambient temperature.

Caution: the outside of the vial is not sterile.

Vial intended for a single use: do not reuse – do not resterilize.

Risks related to reuse of device:

- infection.
- cross-contamination.
- pyrogenicity.

Once the vial of Viscoderm Skinkò or Viscoderm Skinkò E has been opened, use immediately.

Discard any remaining product after use, complying with the procedures in force in the facility.

STORAGE CONDITIONS

- Avoid knocking or bumping
- Store in original secondary package
- Store between 2°C and 30°C
- Do not freeze
- Can be damaged by frost or heat
- Avoid exposure to light

SYMBOLS



Batch code



Use by



Do not use if package is damaged



Attention, see instructions for use



Do not reuse



Do not resterilize



Sterile using aseptic processing techniques



Temperature limitation



Does not contain natural rubber latex



Manufacturer



0499 Notified body number



REVITACARE

Heliparc - 6 rue Saint Simon
Parc d'Activités du Vert Galant
95310 Saint Ouen l'Aumône - FRANCE

Distributed by:

IBSA Farmaceutici Italia srl

Via Martiri di Cefalonia 2,
26900 Lodi ITALY
phone +39.0371.617.1
fax +39.0371.617.244
www.viscoderm.com

Viscoderm Skinkò and Viscoderm Skinkò E are Class III medical devices according to Directive 93/42/EEC, having been granted CE marking in 2009.

VISCODERM®

0.8% - 8 mg/1 ml Hyaluronic acid sodium salt
2.0% - 20 mg/1 ml Hyaluronic acid sodium salt



1 ml pre-filled syringe
Medical device for intra-dermal use
Sterile - Disposable.

DESCRIPTION

Hyaluronic acid (HA) is a polysaccharide which is naturally present in the human body. Its main function consists of maintaining the correct moisturization of the tissues, thanks to its intrinsic capacity to bind a large amount of water.

The sodium salt of hyaluronic acid is formed of repeated chains of disaccharide units of N-acetylglucosamine and sodium glucuronate, and is a fundamentally important component of the extracellular matrix of the majority of tissues, including the skin.

VISCODERM® constitutes a buffered physiological solution of hyaluronic acid.

The hyaluronic acid used is obtained by fermentation and has not been subjected to chemical change processes.

VISCODERM® contains the sodium salt of hyaluronic acid, highly purified and with a molecular weight of around 1 million Daltons, which is very close to the natural molecular weight of endogenous hyaluronic acid. It is undoubtedly important to ensure an appropriate choice of molecular weight of the hyaluronic acid and to come close to the natural molecular weight of endogenous hyaluronic acid, as in this manner the product is rendered totally biocompatible.

The other components of the product are: sodium chloride, sodium phosphate and water for injectable preparations.

INDICATIONS

VISCODERM®, acting through a corrective/filling action of the natural and induced cutaneous hollows, intervenes:

- in the physiological process of ageing of the skin, the effects of which include insipidation of the horny layer and changes in the elastic fibres of the dermis,
- in the dermal tissue repair process, in cases of scar results following superficial cutaneous trauma (e.g. acne and chickenpox scars).

The viscoelastic and moisturizing properties of hyaluronic acid, combined with the possibility to maintain the hyaluronic acid at adequate levels in the cutaneous tissues, allow the moisturizing of the tissues and creation of the optimal condition for preventing and contrasting the skin ageing process, and favour remodelling of the tissue with a consequent corrective effect on scar results on the skin.

Hyaluronic acid also has a role inside the extracellular matrix, creating the physiological conditions for the proliferation, migration and structure of the dermal cell component. Moreover, the intradermal administration of **VISCODERM®** and therefore its action on the dermis rather than on the epidermis, allows an optimal quantity of hyaluronic acid to be brought directly into the tissue to be treated, to contrast the cytotoxic action of free radicals on the fibroblasts, ensuring the effectiveness of preventive and corrective esthetic medicine operations.

The hyaluronic acid used in **VISCODERM®** is produced through the biosynthesis of a natural substrate without further chemical transformation and **VISCODERM®** therefore has excellent biocompatibility and its use in the dermis allows integration of the hyaluronic acid which has been reduced and modified due to the physiological ageing process of the skin or following superficial cutaneous trauma.

Concentration 0.8% - 8mg/1 ml Hyaluronic acid sodium salt: indicated for maintenance of the corrective effect of the treatment.

Concentration 2.0% - 20 mg/1 ml Hyaluronic acid sodium salt: indicated for the initial course of treatment mostly of the face.

An initial course of three treatment sessions at one week intervals is recommended, followed if necessary by monthly maintenance sessions.

PACKS AVAILABLE

- Pack with 1 pre-filled 1 ml syringe in the concentration of 0.8%: 0.8 mg/1 ml Hyaluronic acid sodium salt and 2 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 3 pre-filled 1 ml syringe in the concentration of 0.8%: 0.8 mg/1 ml Hyaluronic acid sodium salt and 6 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 1 pre-filled 1 ml syringe in the concentration of 2.0%: 20 mg/1 ml Hyaluronic acid sodium salt and 2 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 3 pre-filled 1 ml syringe in the concentration of 2.0%: 20 mg/1 ml Hyaluronic acid sodium salt and 6 needles 30G x 1/2" (0,3 x 12 mm).

The pre-filled syringe has been sterilised by moist heat.

The needle has been sterilised by ethylene oxide.

Needle: CE 0197; Manufacturer: Terumo Europe N. V. - Interleuvenlaan 40 - 3001 Leuven, Belgium

PRODUCT DESCRIPTION

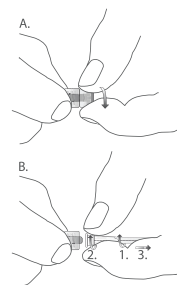
VISCODERM® appears in the form of a glass syringe:

- 1.25 ml containing 1 ml of solution

The content of the syringe is sterile and pyrogen-free.

INSTRUCTIONS FOR USE

- Carefully unscrew the cap of the tip of the syringe, keeping the fingers firmly joined to the luer-lock and being particularly careful to avoid contact with the opening (Figure A).
- Keeping a firm grip on the luer-lock mount of the syringe, secure the 30G needle (included in the pack) by turning it until a slight counter-pressure is felt in order to ensure an air-tight seal and prevent leakage of the liquid during administration (Figure B).
- Inject **VISCODERM®** at room temperature and with strict asepsis conditions.
- Inject **VISCODERM®** intradermally with a linear technique or with picotage at a medium deep level.



WARNINGS

- The content of the pre-filled syringe is sterile. The syringe is packaged in a sealed blister pack.
- The external surface of the syringe is not sterile.
- Do not use **VISCODERM®** after the expiry date shown on the pack.
- Do not use **VISCODERM®** if the packaging is open or damaged.
- The injection site must be on healthy skin.
- Do not inject intravenously, into muscles, tendons or for mammary expansion.
- Do not mix with other products.
- Do not inject into areas where inflammation is present.
- Do not sterilise again. The device was foreseen as a throwaway device only.
- Do not reuse to avoid any risk of contamination.
- Store between 0 - 25 °C away from heat sources. Do not freeze.
- Once opened, **VISCODERM®** must be used immediately and discarded after use.
- It is recommended to change the needle in the middle of the treatment (e.g. to treat the entire face, use 2 distinct needles)
- Keep out of reach and sight of children.
- After the injection and for the following 3-5 days, advise the patient to avoid exposing the treated area to UV rays and to protect it with total block sun-creams.
- The presence of an air bubble does not alter in any way the quality of the product.

SIDE-EFFECTS

Extra-dermal infiltration of **VISCODERM®** can cause undesired effects locally. During the use of **VISCODERM®**, symptoms such as pain, the sensation of heat, reddening or swelling may appear at the injection site. These secondary emergencies can be relieved by applying ice to the treated area. They generally disappear in a short space of time. Doctors must ensure that patients notify them of any undesired effects which occur after the treatment.

CONTRA-INDICATIONS

VISCODERM® must not be used with treatments such as laser resurfacing and medium deep skin-peeling.

PRECAUTIONS FOR USE

Do not concomitantly use disinfectants containing quaternary ammonium salts or chlorhexidine for skin preparation as hyaluronic acid can precipitate in their presence.

INTERACTIONS WITH OTHER DRUGS

None known at present.

TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

THE INTRADERMAL INJECTION MAY ONLY BE ADMINISTERED BY A MEDICAL PRACTITIONER.

LAST PATIENT INFORMATION LEAFLET REVIEW:

October 2018

Pre-filled syringe:

Year of CE certification: 2010



MANUFACTURER:
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2 - 26900 LODI - Italy
e-mail: info@ibsaderma.com



See the instructions for use



Caution: read the warnings carefully



Use by...



Storage temperature



Steam sterilised



Lot



Sterilised by ethylene oxide

EXP. Expiry

VISCODERM[®] trio



1.6% - 1.5 ml Hyaluronic acid sodium salt

Pre-filled 1.5 ml syringe
Medical device for intra-dermal use
Sterile - Disposable.

DESCRIPTION

Hyaluronic acid (HA) is a polysaccharide which is naturally present in the human body. Its main function consists of maintaining the correct moisturization of the tissues, thanks to its intrinsic capacity to bind a large amount of water.

The sodium salt of hyaluronic acid is formed of repeated chains of disaccharide units of N-acetylglucosamine and sodium glucuronate, and is a fundamentally important component of the extracellular matrix of the majority of tissues, including the skin.

VISCODERM[®] trio constitutes a buffered physiological solution of hyaluronic acid.

The hyaluronic acid used is obtained by fermentation and has not been subjected to chemical change processes.

VISCODERM[®] trio contains the sodium salt of hyaluronic acid, highly purified and with a molecular weight of around 1 million Daltons, which is very close to the natural molecular weight of endogenous hyaluronic acid. It is undoubtedly important to ensure an appropriate choice of molecular weight of the hyaluronic acid and to come close to the natural molecular weight of endogenous hyaluronic acid, as in this manner the product is rendered totally biocompatible.

The other components of the product are: sodium chloride, sodium phosphate and water for injectable preparations.

INDICATIONS

VISCODERM[®] trio, acting through a corrective/filling action of the natural and induced cutaneous hollows, intervenes:

- in the physiological process of ageing of the skin, the effects of which include inspissation of the horny layer and changes in the elastic fibres of the dermis,
- in the dermal tissue repair process, in cases of scar results following superficial cutaneous trauma (e.g. acne and chickenpox scars).

The viscoelastic and moisturizing properties of hyaluronic acid, combined with the possibility to maintain the hyaluronic acid at adequate levels in the cutaneous tissues, allow the moisturizing of the tissues and creation of the optimal condition for preventing and contrasting the skin ageing process, and favour remodelling of the tissue with a consequent corrective effect on scar results on the skin.

Hyaluronic acid also has a role inside the extracellular matrix, creating the physiological conditions for the proliferation, migration and structure of the dermal cell component. Moreover, the intradermal administration of **VISCODERM[®] trio** and therefore its action on the dermis rather than on the epidermis, allows an optimal quantity of hyaluronic acid to be brought directly into the tissue to be treated, to contrast the cytotoxic action of free radicals on the fibroblasts, ensuring the effectiveness of preventive and corrective esthetic medicine operations.

The hyaluronic acid used in **VISCODERM[®] trio** is produced through the biosynthesis of a natural substrate without further chemical transformation and **VISCODERM[®] trio** therefore has excellent biocompatibility and its use in the dermis allows integration of the hyaluronic acid which has been reduced and modified due to the physiological ageing process of the skin or following superficial cutaneous trauma.

VISCODERM[®] trio is indicated for the initial course of treatment of large areas and thin, sensitive skin.

An initial course of three treatment sessions at one week intervals is recommended, followed if necessary by monthly maintenance sessions.

PACKS AVAILABLE

Pack with 3 pre-filled 1.5 ml syringes in the concentration of 1.6% - 24 mg/1.5 ml Hyaluronic acid sodium salt and 6 needles 30G x 1/2" (0.3 x 12 mm).

The pre-filled syringe has been sterilised by moist heat.

The needle has been sterilized by ethylene oxide.
Needle: CE 0197; Manufacturer: Terumo Europe N. V. - Interleuvenlaan 40 - 3001 Leuven, Belgium

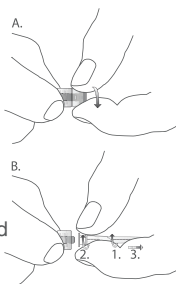
PRODUCT DESCRIPTION

VISCODERM[®] trio appears in the form of a 2.25 ml glass syringe containing 1.5 ml of solution.

The content of the syringe is sterile and pyrogen-free.

INSTRUCTIONS FOR USE

- Carefully unscrew the cap of the tip of the syringe, keeping the fingers firmly joined to the luer-lock and being particularly careful to avoid contact with the opening (Figure A).
- Keeping a firm grip on the luer-lock mount of the syringe, secure the 30G needle (included in the pack) by turning it until a slight counter-pressure is felt in order to ensure an air-tight seal and prevent leakage of the liquid during administration (Figure B).
- Inject **VISCODERM[®] trio** at room temperature and with strict asepsis conditions.
- Inject **VISCODERM[®] trio** intradermally with a linear technique or with picotage at a medium deep level.



WARNINGS

- The content of the pre-filled syringe is sterile. The syringe is packaged in a sealed blister pack.
- The external surface of the syringe is not sterile.
- Do not use **VISCODERM[®] trio** after the expiry date shown on the pack.
- Do not use **VISCODERM[®] trio** if the packaging is open or damaged.
- The injection site must be on healthy skin.
- Do not inject intravenously, into muscles, tendons or for mammary expansion.
- Do not mix with other products.
- Do not inject into areas where inflammation is present.
- Do not sterilise again. The device was foreseen as a throwaway device only.
- Do not reuse to avoid any risk of contamination.
- Store between 0 - 25 °C away from heat sources. Do not freeze.
- Once opened, **VISCODERM[®] trio** must be used immediately and discarded after use.
- It is recommended to change the needle in the middle of the treatment (e.g. to treat the entire face, use 2 distinct needles)
- Keep out of reach and sight of children.
- After the injection and for the following 3-5 days, advise the patient to avoid exposing the treated area to UV rays and to protect it with total block sun-creams.
- The presence of an air bubble does not alter in any way the quality of the product.

PRECAUTIONS FOR USE

Do not concomitantly use disinfectants containing quaternary ammonium salts or chlorhexidine for skin preparation as hyaluronic acid can precipitate in their presence.

INTERACTIONS WITH OTHER DRUGS

None known at present.

SIDE-EFFECTS

Extra-dermal infiltration of **VISCODERM[®] trio** can cause undesired effects locally.

During the use of **VISCODERM[®] trio**, symptoms such as pain, the sensation of heat, reddening or swelling may appear at the injection site. These secondary emergencies can be relieved by applying ice to the treated area. They generally disappear in a short space of time. Doctors must ensure that patients notify them of any undesired effects which occur after the treatment.

CONTRA-INDICATIONS

VISCODERM[®] trio must not be used with treatments such as laser resurfacing and medium deep skin-peeling.

LAST PATIENT INFORMATION LEAFLET REVIEW:

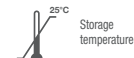
September 2017

TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

THE INTRADERMAL INJECTION MAY ONLY BE ADMINISTERED BY A MEDICAL PRACTITIONER.

Pre-filled syringe:
Year of CE certification: 2010

MANUFACTURER:
IBSA FARMACEUTICI ITALIA srl
Via Martiri di Cefalonia, 2
26900 LODI - ITALY
e-mail: info@ibsaderma.com



VISCODERM®

0.8% - 8 mg/1 ml Hyaluronic acid sodium salt
2.0% - 20 mg/1 ml Hyaluronic acid sodium salt



1 ml pre-filled syringe
Medical device for intra-dermal use
Sterile - Disposable.

DESCRIPTION

Hyaluronic acid (HA) is a polysaccharide which is naturally present in the human body. Its main function consists of maintaining the correct moisturization of the tissues, thanks to its intrinsic capacity to bind a large amount of water.

The sodium salt of hyaluronic acid is formed of repeated chains of disaccharide units of N-acetylglucosamine and sodium glucuronate, and is a fundamentally important component of the extracellular matrix of the majority of tissues, including the skin.

VISCODERM® constitutes a buffered physiological solution of hyaluronic acid.

The hyaluronic acid used is obtained by fermentation and has not been subjected to chemical change processes.

VISCODERM® contains the sodium salt of hyaluronic acid, highly purified and with a molecular weight of around 1 million Daltons, which is very close to the natural molecular weight of endogenous hyaluronic acid. It is undoubtedly important to ensure an appropriate choice of molecular weight of the hyaluronic acid and to come close to the natural molecular weight of endogenous hyaluronic acid, as in this manner the product is rendered totally biocompatible.

The other components of the product are: sodium chloride, sodium phosphate and water for injectable preparations.

INDICATIONS

VISCODERM®, acting through a corrective/filling action of the natural and induced cutaneous hollows, intervenes:

- in the physiological process of ageing of the skin, the effects of which include insipidation of the horny layer and changes in the elastic fibres of the dermis,
- in the dermal tissue repair process, in cases of scar results following superficial cutaneous trauma (e.g. acne and chickenpox scars).

The viscoelastic and moisturizing properties of hyaluronic acid, combined with the possibility to maintain the hyaluronic acid at adequate levels in the cutaneous tissues, allow the moisturizing of the tissues and creation of the optimal condition for preventing and contrasting the skin ageing process, and favour remodelling of the tissue with a consequent corrective effect on scar results on the skin.

Hyaluronic acid also has a role inside the extracellular matrix, creating the physiological conditions for the proliferation, migration and structure of the dermal cell component. Moreover, the intradermal administration of **VISCODERM®** and therefore its action on the dermis rather than on the epidermis, allows an optimal quantity of hyaluronic acid to be brought directly into the tissue to be treated, to contrast the cytotoxic action of free radicals on the fibroblasts, ensuring the effectiveness of preventive and corrective esthetic medicine operations.

The hyaluronic acid used in **VISCODERM®** is produced through the biosynthesis of a natural substrate without further chemical transformation and **VISCODERM®** therefore has excellent biocompatibility and its use in the dermis allows integration of the hyaluronic acid which has been reduced and modified due to the physiological ageing process of the skin or following superficial cutaneous trauma.

Concentration 0.8% - 8mg/1 ml Hyaluronic acid sodium salt: indicated for maintenance of the corrective effect of the treatment.

Concentration 2.0% - 20 mg/1 ml Hyaluronic acid sodium salt: indicated for the initial course of treatment mostly of the face.

An initial course of three treatment sessions at one week intervals is recommended, followed if necessary by monthly maintenance sessions.

PACKS AVAILABLE

- Pack with 1 pre-filled 1 ml syringe in the concentration of 0.8%: 0.8 mg/1 ml Hyaluronic acid sodium salt and 2 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 3 pre-filled 1 ml syringe in the concentration of 0.8%: 0.8 mg/1 ml Hyaluronic acid sodium salt and 6 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 1 pre-filled 1 ml syringe in the concentration of 2.0%: 20 mg/1 ml Hyaluronic acid sodium salt and 2 needles 30G x 1/2" (0,3 x 12 mm).
- Pack with 3 pre-filled 1 ml syringe in the concentration of 2.0%: 20 mg/1 ml Hyaluronic acid sodium salt and 6 needles 30G x 1/2" (0,3 x 12 mm).

The pre-filled syringe has been sterilised by moist heat.

The needle has been sterilised by ethylene oxide.

Needle: CE 0197; Manufacturer: Terumo Europe N. V. - Interleuvenlaan 40 - 3001 Leuven, Belgium

PRODUCT DESCRIPTION

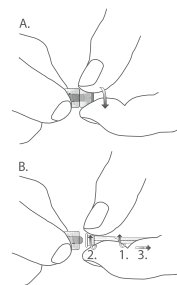
VISCODERM® appears in the form of a glass syringe:

- 1.25 ml containing 1 ml of solution

The content of the syringe is sterile and pyrogen-free.

INSTRUCTIONS FOR USE

- Carefully unscrew the cap of the tip of the syringe, keeping the fingers firmly joined to the luer-lock and being particularly careful to avoid contact with the opening (Figure A).
- Keeping a firm grip on the luer-lock mount of the syringe, secure the 30G needle (included in the pack) by turning it until a slight counter-pressure is felt in order to ensure an air-tight seal and prevent leakage of the liquid during administration (Figure B).
- Inject **VISCODERM®** at room temperature and with strict asepsis conditions.
- Inject **VISCODERM®** intradermally with a linear technique or with picotage at a medium deep level.



WARNINGS

- The content of the pre-filled syringe is sterile. The syringe is packaged in a sealed blister pack.
- The external surface of the syringe is not sterile.
- Do not use **VISCODERM®** after the expiry date shown on the pack.
- Do not use **VISCODERM®** if the packaging is open or damaged.
- The injection site must be on healthy skin.
- Do not inject intravenously, into muscles, tendons or for mammary expansion.
- Do not mix with other products.
- Do not inject into areas where inflammation is present.
- Do not sterilise again. The device was foreseen as a throwaway device only.
- Do not reuse to avoid any risk of contamination.
- Store between 0 - 25 °C away from heat sources. Do not freeze.
- Once opened, **VISCODERM®** must be used immediately and discarded after use.
- It is recommended to change the needle in the middle of the treatment (e.g. to treat the entire face, use 2 distinct needles)
- Keep out of reach and sight of children.
- After the injection and for the following 3-5 days, advise the patient to avoid exposing the treated area to UV rays and to protect it with total block sun-creams.
- The presence of an air bubble does not alter in any way the quality of the product.

SIDE-EFFECTS

Extra-dermal infiltration of **VISCODERM®** can cause undesired effects locally. During the use of **VISCODERM®**, symptoms such as pain, the sensation of heat, reddening or swelling may appear at the injection site. These secondary emergencies can be relieved by applying ice to the treated area. They generally disappear in a short space of time. Doctors must ensure that patients notify them of any undesired effects which occur after the treatment.

CONTRA-INDICATIONS

VISCODERM® must not be used with treatments such as laser resurfacing and medium deep skin-peeling.

PRECAUTIONS FOR USE

Do not concomitantly use disinfectants containing quaternary ammonium salts or chlorhexidine for skin preparation as hyaluronic acid can precipitate in their presence.

INTERACTIONS WITH OTHER DRUGS

None known at present.

TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

THE INTRADERMAL INJECTION MAY ONLY BE ADMINISTERED BY A MEDICAL PRACTITIONER.

LAST PATIENT INFORMATION LEAFLET REVIEW:

October 2018

Pre-filled syringe:

Year of CE certification: 2010



MANUFACTURER:
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2 - 26900 LODI - Italy
e-mail: info@ibsaderma.com



See the instructions for use



Caution: read the warnings carefully



Use by...



Storage temperature



Steam sterilised



Lot



Sterilised by ethylene oxide

EXP. Expiry



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