SINOVIAL HL®

3.2% - 16 mg (H-HA) + 16 mg (L-HA)/1 ml Hyaluronic acid sodium salt
3.2% - 32 mg (H-HA) + 32 mg (L-HA)/2 ml Hyaluronic acid sodium salt

Joint viscosupplementation device
Sterile - Single-use

DESCRIPTION

Hyaluronic acid sodium salt is formed by repetitive chains of disaccharide units of N-acetylglucosamine and sodium glucuronate and is an essential component of the synovial fluid giving it particular viscoelastic properties.

SINOVIAL HL® is composed of a buffered saline solution of high molecular weight (H-HA) and low molecular weight (L-HA) hyaluronic acid.

The high- and low-molecular-weight hyaluronic acid used in the device is obtained by fermentation and has not undergone chemical modification processes. This results in excellent tolerability.

In addition, the HA chains with different molecular weight present in **SINOVIAL HL®**, thanks to a specific and patented treatment of the solution, interact with each other, giving **SINOVIAL HL®** unique rheological properties that allow higher concentrations of hyaluronic acid to be administered at equal viscosity of the solution.

The HA chains with a different molecular weight provide greater resistance to hyaluronidase as this enzyme is unable to recognize the conformation of these high-molecular-weight complexes, therefore, **SINOVIAL HL®** is more suitable for in vivo applications in tissues.

INTENDED USE

SINOVIAL HL® with its particular formula belongs to the latest generation of intra-articular treatments**. SINOVIAL HL®** is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. **SINOVIAL HL®** reduces pain in the joint and encourages recovery of the associated joint mobility. Clinical data have demonstrated that SINOVIAL HL, in combination with the laser terapy, can improve the symptomatology correlated to the tendinopathy.

INDICATIONS

SINOVIAL HL® is indicated in case of pain or reduced mobility due to degenerative affections (e.g. arthrosis), post-traumatic disorders associated with acute and chronic articular disability in the large and small joints.

INTENDED POPULATION AND USERS

SINOVIAL HL® is indicated for adults of both sexes and is to be administered by intra-articular injection by qualified personnel only.

COMPOSITION

SINOVIAL HL® has consisted by the prefilled syringe with 1 or 2 ml of solution, which contains:

SYRINGE VOLUME	**1 ml**	**2 ml**
FUNCTIONAL COMPONENT		
SODIUM HYALURONATE	16 mg (H-HA) + 16 mg (L-HA)	32 mg (H-HA) + 32 mg (L-HA)
OTHER COMPONENTS		
SODIUM CHLORIDE	8.000 mg	16.000 mg
SODIUM PHOSPHATE	0.205 mg	0.410 mg
WATER FOR INJECTION	q.s. 1.0 ml	q.s. 2.0 ml

POSOLOGY

It is advisable to do 1 infiltration a week up to a maximum of 3 infiltrations per treatment cycle. The appropriateness and frequency with which the treatment cycle can be repeated must be assessed by the physician, in any case considering the risk/benefit ratio for each individual patient.

AVAILABLE KITS

SINOVIAL HL® is available in kits of 1 prefilled syringe in the following volumes:

- 1 ml prefilled syringe (16 mg (H-HA) + 16 mg (L-HA) of hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution) and one 21G x 1½" (0.8 x 40 mm) needle
- 1 ml prefilled syringe (16 mg (H-HA) + 16 mg (L-HA) of hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution) and two needles:
  - _1 ago 22 G x 1 ½" (0,7 x 40 mm);
  - _1 ago 29 G x ½" TW (0,3 x 12 mm);
- 2 ml prefilled syringe (32 mg (H-HA) + 32 mg (L-HA) of hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution) and one 21G x 1½" (0.8 x 40 mm) needle.

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

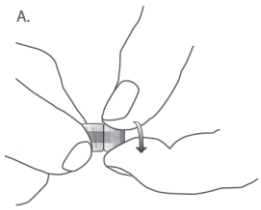
Prefilled syringe sterilized by moist heat.

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

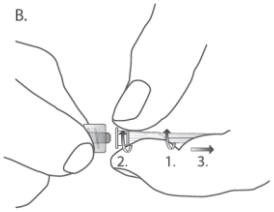
Needles sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOVIAL HL®**.
- Carefully unscrew the syringe cap, firmly holding the Luer-lock closing neck between your fingers and being particularly careful to avoid contact with the opening (Figure A).



- Firmly holding the Luer-lock closing neck between your fingers, screw the 21G needle (included in the kit) tightly onto the closing neck of the syringe until you feel slight pressure so as to ensure an airtight seal and prevent liquid leakage during administration (Figure B).



- Inject **SINOVIAL HL®** at ambient temperature and in strict aseptic conditions.
- Inject **SINOVIAL HL®** into the synovial space of the joint or into the tendon sheath/peritendinous area depending on the medical need identified.

After the treatment:

Fill in the *Implant Card* and provide it to the patient.

Note: For each prefilled syringe used for treatment, fill in one *Implant Card* (i.e. 1 prefilled syringe used = 1 *Implant Card* filled)

Each *Implant Card* is located inside the box; to remove it, follow these steps:

A. open the BRANDNAME box.

B. remove all blister packs, containing prefilled syringes, from the box.

C. detach the *Implant C*ard from inside the box; gently press down the blue outlined area on the external box (back face), taking care not to break it.

Instruction for completing the Implant card

Fill in the fields marked with the following symbols with the information indicated:

	Patient Name or patient ID
	Date of treatment

	Name and address of the implanting healthcare institution Name of medical practioner**.**

WARNINGS

- The content of the prefilled syringe is sterile. The syringe and needles are packed in a sealed blister pack.
- The outer surface of the syringe is not sterile.
- Do not use **SINOVIAL HL®** after the expiry date indicated on the package.
- Do not use **SINOVIAL HL®** if the packaging is open or damaged, because the sterility of the product could be compromised - The injection site must be on healthy skin.
- Do not use in pregnant or breast-feeding women.
- Do not use in patients with autoimmune diseases.
- Do not inject intravascularly. Do not inject outside the joint cavity, into the synovial tissue or into the articular capsule.
- Do not administer **SINOVIAL HL®** in the presence of heavy intra-articular effusion.
- Do not resterilize. The device is intended for single use only.
- Do not reuse in order to prevent any risk of contamination.
- Store at ambient temperature below 25°C and away from heat sources. Do not freeze.
- Once opened, **SINOVIAL HL®** must immediately be used and discarded after use.
- SINOVIAL HL® is indicated for adult patients.
- Keep out of the reach and sight of children.
- After injection, advise the patient to avoid any intense physical activity and to resume his or her normal activities only after several days.
- Any air bubble present does not compromise the characteristics of the product.
- Do not use SINOVIAL HL® in case of known hypersensitivity or allergies to the components of the product

PRECAUTIONS FOR USE

Do not mix **SINOVIAL HL®** with disinfectants such as quaternary ammonium salts or chlorhexidine as a precipitate may form.

INTERACTIONS

Based on the in-vitro data available to date, there are no known chemical-physical and biological interactions between **SINOVIAL HL®** and Plasma-Rich Platelets (PRP), used for the endoarticular infiltrative treatment of osteoarthritis.

To date, there are no known interactions between **SINOVIAL HL®** and other drugs/treatments. Nonetheless, in case of therapies and/or taking medications in conjunction with the treatment, consult your doctor for more information.

SIDE EFFECTS

Extra-articular infiltration of **SINOVIAL HL®** may locally cause undesirable effects.

During use of **SINOVIAL HL®**, symptoms such as pain, sensation of heat, reddening or swelling may occur at the injection site. These secondary manifestations can be relieved by applying ice on the treated area.
They generally disappear after a short period of time. Physicians must ensure that patients notify them of any undesirable effects that occur after the treatment.
In the event of an incident, inform the manufacturer or the competent authority.

OVERDOSE

Follow the posology indicated and if you experience any side effects related to an overdose, contact your doctor or nearest hospital.

CONTRAINDICATIONS

SINOVIAL HL® should not be injected in the presence of an infected or severely inflamed joint or if the patient has a skin affection or infection in the injection site area.

Shelf-life: 36 months.
The expiry date indicates the maximum shelf-life of the medical device.

DATE OF LAST REVISION OF PACKAGE LEAFLET

January 2022

DISPOSAL

Do not dispose of the product in the environment after use. Follow local regulations for disposal of the product.

To the following link it's possible to download the Summary of Safety and Clinical Performance:

https://www.ibsa.it/ibsa-farmaceutici/summary-of-safety-and-clinical-performance.html

Manufacturer:

IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2 – 26900 Lodi – Italy
E-mail: info@ibsa.it
www.sinovial.it

Distributor:

(name and address of distributor)

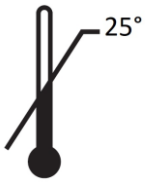
CE 0477

See the instructions for use

Caution ! Read the warnings carefully

Use by...

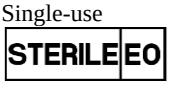
Single-use



Storage temperature

Sterilized by moist heat

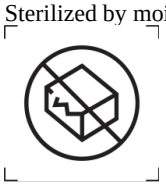
Batch



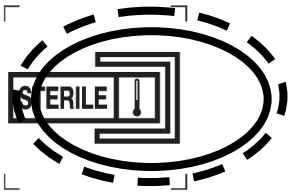
Sterilized by ethylene oxide

Exp.

Expiry



Do not use if the package is damaged



The medical device contains a sterile fluid path that has been sterilized by moist heat. Moreover indicates a single *sterile* barrier system with protective packaging outside.

Medical Device

Date of manufacture

Do not resterilize

Unique device identifier

Manufacturer