SINOGEL® 3 ml

2.4% sodium hyaluronate and 1.6% sodium chondroitin

Joint visco-supplementation device

3ml prefilled syringe

DESCRIPTION

Osteoarthritis (OA) is a chronic degenerative disease characterized by progressive damage of joint cartilage, reduction of joint space, subchondral bone re-modelling, formation of marginal joint osteophytes and synovitis. An optimal OA therapy is intra-articular injection of exogenous hyaluronic acid, which can relieve the symptoms thanks to restoration of the viscoelastic properties of the synovial fluid.

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, where it acts as joint lubricant during shear stress and as shock absorber during compressive stress.

SINOGEL® 3 ml is composed of a buffered saline solution of highly purified hyaluronic acid with high molecular weight and sodium chondroitin of biotechnological origin. The hyaluronic acid used in the device is obtained by fermentation and has not undergone chemical modification processes. This results in excellent tolerability.

INTENDED USE

SINOGEL® with its particular formula and its high concentration of glycosaminoglycans (GAG) belongs to the latest generation of intra-articular treatments and is specifically designed for visco-supplementation of large joints for which a large volume of solution with a high concentration of hyaluronic acid without high viscosity is recommended. Thanks to a specific and patented treatment of the solution, the hyaluronic acid and sodium chondroitin chains present in the device interact with each other giving the solution rheological properties such as to obtain viscosity values lower than those of only hyaluronic acid at the same concentration.

INDICATIONS

SINOGEL® 3ml is indicated for pain or reduced mobility due to degenerative affections, post-traumatic disorders or joint alterations. **SINOGEL**® is a device for integration of the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. Restoring the viscoelastic properties of the synovial fluid, **SINOGEL**® reduces pain and restores joint mobility.

INTENDED POPULATION AND USERS

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

SINOGEL® IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

SINOGEL® has consisted by the prefilled syringe with 3 ml of solution, which contains:

FUNCTIONAL COMPONENT	
SODIUM HYALURONATE	72 mg
SODIUM CONDROITIN	48 mg
OTHER COMPONENTS	
SODIUM CHLORIDE	21.000 mg
MONOBASIC SODIUM PHOSPHATE	0,135 mg
DIBASIC SODIUM PHOSPHATE	0,48 mg
WATER FOR INJECTION	q.s. 3.0 ml

POSOLOGY

It is advisable to do 1 infiltration 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

SINOGEL® is available in kits of 1 prefilled syringe (72.0mg hyaluronic acid sodium salt and 48.0mg sodium chondroitin in 3ml sodium chloride buffered saline solution) and one 21G x 1½" (0.8 x 40 mm) needle.

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

Prefilled syringe sterilized by moist heat.

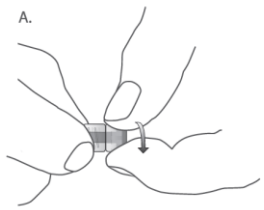
Needle sterilized by ethylene oxide.

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

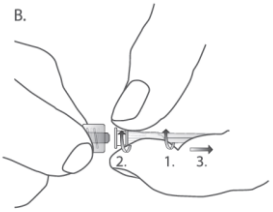
INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOGEL**® 3 ml.

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 **SINOGEL®** 3 ml at ambient temperature and in strict aseptic conditions. For visco-supplementation of hip osteoarthritis, it is advisable to inject using an ultrasound guide.
- Inject **SINOGEL®** 3ml only into the synovial space.

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 is packed in a sealed blister pack.
- The outer surface of the syringe is not sterile.
- Do not use the device after the expiry date indicated on the package.
- Do not use the device 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 **SINOGEL**® in the presence of heavy intra-articular effusion.
- Do not re-sterilize. 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, the device must immediately be used and discarded after use.
- **SINOGEL**® is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use **SINOGEL**® in case of known hypersensitivity or allergies to the components of the product.
- After the intra-articular injection advise the patient to avoid any intense physical activity and to resume his or her normal activities only after several days.
- Protect from sunlight.
- Any air bubble present does not compromise the characteristics of the product.

PRECAUTIONS FOR USE

Do not mix the device with disinfectants such as quaternary ammonium salts or chlorhexidine as a precipitate may form.

INTERACTIONS

To date, there are no known interactions between **SINOGEL**® 3 ml and other drugs/treatments. Nonetheless, in case of therapies and/or taking medications in conjunction with the treatment, consult your doctor for more information.

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SIDE EFFECTS

Extra-articular infiltration of **SINOGEL**® 3 ml may locally cause undesirable effects.
During use of **SINOGEL**® 3 ml, 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 joint.
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

SINOGEL® 3 ml 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

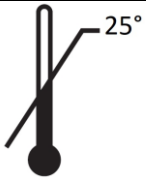
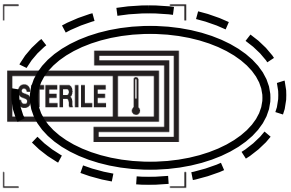
DISPOSAL

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:
(nome e indirizzo del distributore)

CE **0477**	 See the instructions for use	 Do not resterilize	 Use by...
 Single-use	 Storage temperature	 Sterilized by moist heat	 Batch
 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.	 **Caution ! Read the warnings carefully**	 Unique device identifier
 Medical Device	 Date of manufacture	 Sterilized by ethylene oxide	**Exp.** Expiry
 Manufacturer			