SINOGEL

2.4% Sodium hyaluronate and 1.6% Sodium chondroitin

3 ml Pre-filled syringe

DESCRIPTION

SINOGEL constitutes a buffered physiological solution of highly purified sodium hyaluronate, with high molecular weight, and Sodium chondroitin of biotechnological origin. The other components of the product are: Sodium chloride, sodium phosphate and water for injections. Hyaluronic Acid contained in the device is obtained through fermentation process and it is not chemically modified. This leads to an excellent tolerability.
The hyaluronic acid chains and the sodium chondroitin chains contained in the device, thanks to a specific and patented treatment of the solution, interact each other providing to the solution rheological characteristics such as to obtain the viscosity values lower than the ones of the only hyaluronic acid at the same concentration.

FREQUENCY OF USE

SINOGEL is intended to be injected only once for each cycle of treatment.
If necessary, further injections may be administered. It is the doctor's responsibility to evaluate the appropriateness of repeating the treatment and its frequency for each patient, taking into consideration the risk/benefit ratio of the treatment in each case.

PACKS AVAILABLE

Pack of 1 pre-filled syringe (72.0 mg hyaluronic acid sodium salt and 48.0 mg of sodium chondroitin in 3 ml buffered physiological solution of sodium chloride) and one 21 G x 1 ½" (0.8 x 40 mm) needle.

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

The needle has been sterilized by ethylene oxide. CE 0197

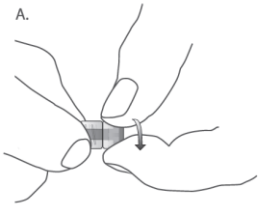
Manufacturer: Terumo Europe N. V. – Interleuvenlaan 40 – 3001 Leuven, Belgium

PRODUCT DESCRIPTION

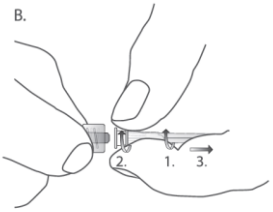
SINOGEL appears in the form of 3.25 ml glass syringe containing 3 ml of solution.
The content of the syringe is sterile and pyrogen-free.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOGEL.**
- 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).



- Secure the needle on the luer-lock mount (a suitable needle), screwing it tight until a slight counter-pressure is felt in order to ensure an air-tight seal and prevent leakage of the liquid during administration, keeping the fingers firmly joined to the luer-lock (Figure B).



- Inject **SINOGEL** at room temperature and with strict asepsis conditions. For the intra-articular injection into the hip joint an Ultrasound-Guided procedure is suggested.
- Inject **SINOGEL** only into the synovial space.

WARNING

- 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 the device after the expiry date shown on the pack.
- Do not use the device if the packaging is open or damaged.
- Do not sterilize again. The device was foreseen as a throwaway device only.
- Do not reuse to avoid any risk of contamination.
- Once opened, the device must be used immediately and discarded after use.
- The injection site must be on healthy skin.
- Do not inject intravenously. Do not inject outside the joint cavity, into the synovial tissue or into the articular capsule.
- Do not administer the device in the presence of heavy intra-articular effusion.
- 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.
- Store between 0 - 25° C away from heat sources. Do not freeze.
- Keep away from sunlight.
- Keep out of reach and sight of children.

PRECAUTIONS FOR USE

Do not mix the device with disinfectants containing quaternary ammonium salts or chlorhexidine, as hyaluronic acid can precipitate in their presence.

INTERACTIONS WITH OTHER DRUGS

None known at present.

SIDE-EFFECTS

Extra-articular seepage of **SINOGEL** may cause undesired effects locally.
During the use of **SINOGEL**, symptoms such as pain, the sensation of heat, reddening or swelling may appear at the injection site. These secondary emergences can be relieved by applying ice to the treated joint. 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
SINOGEL must not be injected in the presence of an infected or seriously inflamed joint or if the patient has a cutaneous disease or an infection in the area of the injection site.

THE INJECTION MAY ONLY BE ADMINISTERED BY A MEDICAL PRACTITIONER.

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

Last patient information leaflet review: November2019

Manufacturer:
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2 - 26900 LODI - ITALY
E-mail: info@ibsa.it

DISTRIBUTOR:
(Name and address of the Distributor)

CE 0373

See the instructions for use

Use by…

Protect from sunlight

Disposable

Storage temperature

Steam sterilised

Lot

Do not use if package is damaged

Medical device contains a sterile fluid path that has been sterilized using steam