SINOVIAL®
0.8% 8mg/1ml hyaluronic acid sodium salt
Joint viscosupplementation device
Sterile - Single-use

DESCRIPTION

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. This therapeutic action is expressed by the particular characteristics of the hyaluronic acid used.
SINOVIAL® is composed of a buffered saline solution of hyaluronic acid sodium salt with viscoelastic properties, obtained by fermentation and not chemically modified, and has excellent tolerability. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** reduces pain and restores joint and tendon mobility.
SINOVIAL® acts only in the area where it is injected without any systemic action.
SINOVIAL® contains 0.8% highly purified hyaluronic acid sodium salt with a molecular weight between 800 and 1.200 KDalton.
Hyaluronic acid sodium salt (hyaluronan) 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.

INTENDED USE

SINOVIAL® is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints and tendons. **SINOVIAL®** reduces pain in the joint and encourages recovery of the associated joint and tendon mobility, acting only in the synovial cavity into which it is injected.

INDICATIONS

SINOVIAL® 0.8% /1 ml is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** is indicated in case of pain or reduced mobility due to degenerative affections (e.g. arthrosis), post-traumatic disorders or joint and tendon alterations (e.g. acute and chronic tendinopathy) of the large and small joints. **SINOVIAL®** reduces pain and restores joint and tendon mobility.

INTENDED POPULATION AND USERS

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

COMPOSITION

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

SYRINGE VOLUME	**1 ml**
FUNCTIONAL COMPONENT	
SODIUM HYALURONATE	8.000 mg
OTHER COMPONENTS	
SODIUM CHLORIDE	8.500 mg
SODIUM PHOSPHATE	0.205 mg
WATER FOR INJECTION	q.s. 1.0 ml

POSOLOGY

It is advisable to do 1 infiltration a week up to a maximum of 5 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® is available in kits of 1, 3 and 5 syringes with one 21G x 1½" needle in the following volumes:
- Prefilled syringes (8 mg hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution).

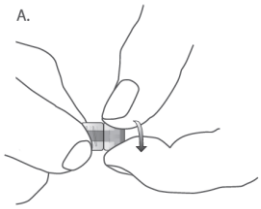
The content of the syringe is sterile and pyrogen-free.
Prefilled syringe sterilized by moist heat.

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

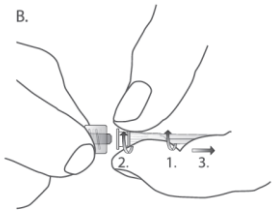
Needle sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOVIAL**®.
- 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**® at ambient temperature and in strict aseptic conditions. Inject **SINOVIAL**® 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 is packed in a sealed blister pack. - The outer surface of the syringe is not sterile.
- Do not use **SINOVIAL**® after the expiry date indicated on the package.
- Do not use **SINOVIAL**® 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**® 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**® must immediately be used and discarded after use.
- **SINOVIAL**® is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use **SINOVIAL**® in case of known hypersensitivity or allergies to the components of the product.
- 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.

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

INTERACTIONS
To date, there are no known interactions between **SINOVIAL**® 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**® may locally cause undesirable effects.
During use of **SINOVIAL**®, 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® 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 referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET
February 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)

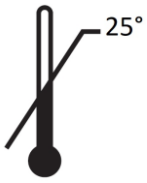
CE 0477


See the instructions for use


Carefully read the warnings


Use by...


Single-use

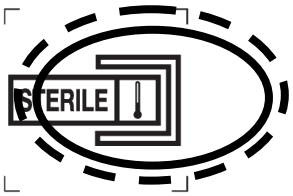


Storage temperature

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.

Sterilized by ethylene oxide

Exp.
Expiry

Medical Device


Date of manufacture

Unique device identifier

Do not resterilize


Manufacturer

SINOVIAL®
0.8% 16mg/2ml hyaluronic acid sodium salt
Joint viscosupplementation device
Sterile - Single-use

DESCRIPTION

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. This therapeutic action is expressed by the particular characteristics of the hyaluronic acid used.
SINOVIAL® is composed of a buffered saline solution of hyaluronic acid sodium salt with viscoelastic properties, obtained by fermentation and not chemically modified, and has excellent tolerability. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** reduces pain and restores joint and tendon mobility.
SINOVIAL® acts only in the area where it is injected without any systemic action.
SINOVIAL® contains 0.8% highly purified hyaluronic acid sodium salt with a molecular weight between 800 and 1.200 KDalton.
Hyaluronic acid sodium salt (hyaluronan) 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.

INTENDED USE

SINOVIAL® is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints and tendons. **SINOVIAL®** reduces pain in the joint and encourages recovery of the associated joint and tendon mobility, acting only in the synovial cavity into which it is injected.

INDICATIONS

SINOVIAL® 0.8% /2 ml is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** is indicated in case of pain or reduced mobility due to degenerative affections (e.g. arthrosis), post-traumatic disorders or joint and tendon alterations (e.g. acute and chronic tendinopathy) of the large and small joints. **SINOVIAL®** reduces pain and restores joint and tendon mobility.

INTENDED POPULATION AND USERS

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

COMPOSITION

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

SYRINGE VOLUME	**2 ml**
FUNCTIONAL COMPONENT	
SODIUM HYALURONATE	16.000 mg
OTHER COMPONENTS	
SODIUM CHLORIDE	17.000 mg
SODIUM PHOSPHATE	0.410 mg
WATER FOR INJECTION	q.s. 2.0 ml

POSOLOGY

It is advisable to do 1 infiltration a week up to a maximum of 5 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® is available in kits of 1, 3 and 5 syringes with one 21G x 1½" needle in the following volumes:
- Prefilled syringes (16.0 mg hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution).

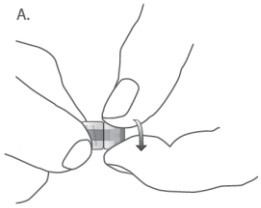
The content of the syringe is sterile and pyrogen-free.
Prefilled syringe sterilized by moist heat.

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

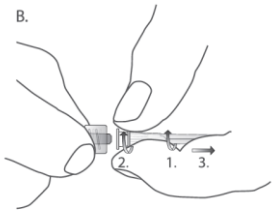
Needle sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOVIAL**®.
- 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**® at ambient temperature and in strict aseptic conditions. Inject **SINOVIAL**® 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 is packed in a sealed blister pack. - The outer surface of the syringe is not sterile.
- Do not use **SINOVIAL**® after the expiry date indicated on the package.
- Do not use **SINOVIAL**® 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**® 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**® must immediately be used and discarded after use.
- **SINOVIAL**® is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use **SINOVIAL**® in case of known hypersensitivity or allergies to the components of the product.
- 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.

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

INTERACTIONS
To date, there are no known interactions between **SINOVIAL**® 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**® may locally cause undesirable effects.
During use of **SINOVIAL**®, 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® 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 referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET
February 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)

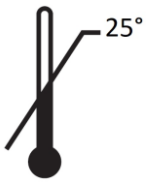
CE 0477


See the instructions for use


Carefully read the warnings


Use by...


Single-use

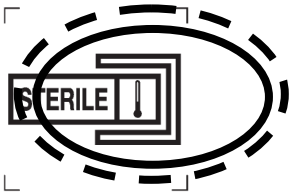


Storage temperature

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.

Sterilized by ethylene oxide

Exp.
Expiry

Medical Device


Date of manufacture

Unique device identifier

Do not resterilize


Manufacturer

SINOVIAL®
1.6% 32mg/2ml Hyaluronic acid sodium salt
Joint viscosupplementation device
Sterile - Single-use

DESCRIPTION

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. This therapeutic action is expressed by the particular characteristics of the hyaluronic acid used. **SINOVIAL®** is composed of a buffered saline solution of hyaluronic acid sodium salt with viscoelastic properties, obtained by fermentation and not chemically modified, and has excellent tolerability. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** reduces pain and restores joint mobility.
SINOVIAL® acts only in the area where it is injected without any systemic action.
SINOVIAL® contains 1.6% highly purified hyaluronic acid sodium salt with a molecular weight between 800 and 1.200 kDalton.
Hyaluronic acid sodium salt (hyaluronan) 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.

INTENDED USE

SINOVIAL® is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. **SINOVIAL®** reduces pain in the joint and encourages recovery of joint mobility, acting only in the synovial cavity into which it is injected.

INDICATIONS

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** is indicated in case of pain or reduced mobility due to degenerative diseases (e. g. arthrosis) and post-traumatic disorders of the large joints. **SINOVIAL®** reduces pain and restores joint mobility.

INTENDED POPULATION AND USERS

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

SINOVIAL® IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

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

SYRINGE VOLUME	**2 ml**
FUNCTIONAL COMPONENT	
SODIUM HYALURONATE	32.000
OTHER COMPONENTS	
SODIUM CHLORIDE	17.000 mg
SODIUM PHOSPHATE	0.410 mg

WATER FOR INJECTION	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® is available in kits of 1, 3 and 5 syringes with one 21G x ½" needle:

- Prefilled syringes (32.0 mg hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution).

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

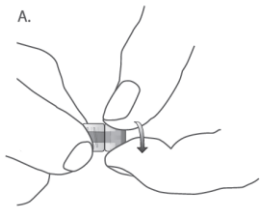
Prefilled syringe sterilized by moist heat.

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

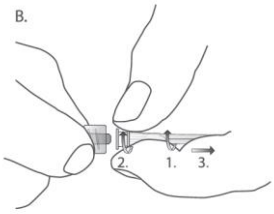
Needle sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOVIAL**®.
- 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**® at ambient temperature and in strict aseptic conditions.

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 **SINOVIAL**® after the expiry date indicated on the package.
- Do not use **SINOVIAL**® 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**® 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**® must immediately be used and discarded after use.
- **SINOVIAL**® is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use **SINOVIAL**® in case of known hypersensitivity or allergies to the components of the product.
- 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.

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

INTERACTIONS
To date, there are no known interactions between **SINOVIAL**® 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**® may locally cause undesirable effects.
During use of **SINOVIAL**®, 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® 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 referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET
February 2022

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

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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)

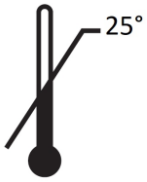
CE 0477


See the instructions for use


Carefully read the warnings


Use by...


Single-use

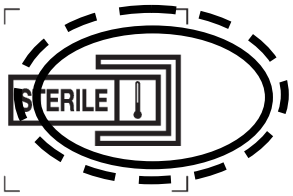


Storage temperature

Sterilized by moist heat

Batch


Do not use if the package is damaged



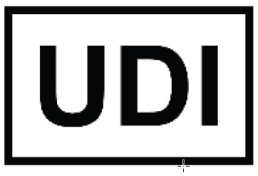
The medical device contains a sterile fluid path that has been sterilized by moist heat. Moreover indicates a single *sterile* barrier system with protective packaging outside.

Sterilized by ethylene oxide

Exp.
Expiry

Medical Device


Date of manufacture



Unique device identifier

Do not resterilize


Manufacturer

SINOVIAL®
2.0% 50 mg/2.5 ml Hyaluronic acid sodium salt
Joint viscosupplementation device
Sterile - Single-use

DESCRIPTION

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. This therapeutic action is expressed by the particular characteristics of the hyaluronic acid used. **SINOVIAL®** is composed of a buffered saline solution of hyaluronic acid sodium salt with viscoelastic properties, obtained by fermentation and not chemically modified, and has excellent tolerability. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** 2.0% reduces pain and restores joint and tendon mobility.
SINOVIAL® acts only in the area where it is injected without any systemic action.

SINOVIAL® contains 2.0% highly purified hyaluronic acid sodium salt with a molecular weight between 800 and 1.200 kDalton.
Hyaluronic acid sodium salt (hyaluronan) 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.

INTENDED USE

SINOVIAL® is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. **SINOVIAL®** reduces pain in the joint and encourages recovery of the associated joint and tendon mobility, acting only in the synovial cavity into which it is injected.

INDICATIONS

SINOVIAL® is a substitute for the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints. Restoring the viscoelastic properties of the synovial fluid, **SINOVIAL®** is indicated in case of pain or reduced mobility due to degenerative affections (e. g. arthrosis) and post-traumatic disorders of the large joints. **SINOVIAL®** reduces pain and restores joint mobility.

INTENDED POPULATION AND USERS

SINOVIAL® is indicated for adults of both sexes and is to be administered by intra-articular injection by qualified personnel only.
SINOVIAL® IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

SINOVIAL® has consisted by the prefilled syringe with 2,5 ml of solution, which contains:

SYRINGE VOLUME	**2,5 ml**
FUNCTIONAL COMPONENT	
SODIUM HYALURONATE	50.000 mg
OTHER COMPONENTS	
SODIUM CHLORIDE	21.250 mg
SODIUM PHOSPHATE	0.513 mg

WATER FOR INJECTION	q.s. 2.5 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

SINOVIAL® is available in kits of 1 syringe with one 21G x 1½" (0.8 x 40 mm) needle in the following volumes:
- Prefilled syringe (50.0 mg hyaluronic acid sodium salt in 2.5 ml sodium chloride buffered saline solution).

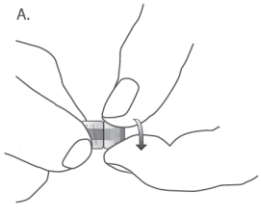
The content of the syringe is sterile and pyrogen-free.
Prefilled syringe sterilized by moist heat.

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

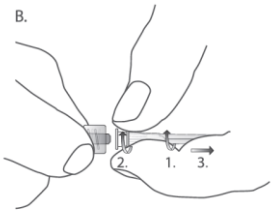
Needle sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Aspirate any joint effusion before proceeding with the injection of **SINOVIAL**®.
- 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**® at ambient temperature and in strict aseptic conditions.

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 **SINOVIAL**® after the expiry date indicated on the package.
- Do not use **SINOVIAL**® 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**® 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**® must immediately be used and discarded after use.
- **SINOVIAL**® is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use **SINOVIAL**® in case of known hypersensitivity or allergies to the components of the product.
- 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.

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

INTERACTIONS
To date, there are no known interactions between **SINOVIAL**® 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**® may locally cause undesirable effects.
During use of **SINOVIAL**®, 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® 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 referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET
February 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)

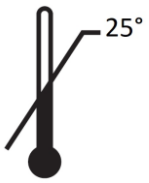
CE 0477

See the instructions for use

Carefully read the warnings

Use by...

Single-use



Storage temperature

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Batch

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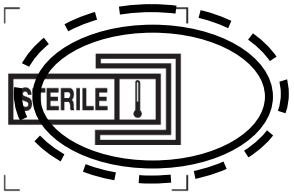

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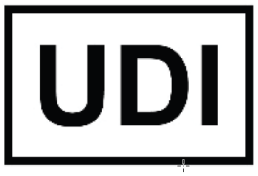

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