# SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
# (for patients)

VISCO-SUPPLETIVE JOIN DEVICE

0.8% - 8 mg / 1 ml hyaluronic acid sodium salt (Mini)

0.8% - 16 mg / 2 ml hyaluronic acid sodium salt

1.6% - 32 mg / 2 ml hyaluronic acid sodium salt (Forte/Highvisc)

2.0 % - 50 mg / 2.5 ml hyaluronic acid sodium salt (One/Once)

With the following brand names:

Sinovial

Intragel

Gony Alert MD

Jointex 1

in accordance with Medical Device Regulation (EU) 2017/745

Manufacturer

IBSA Farmaceutici Italia srl

Via Martiri di Cefalonia 2, 26900 Lodi -Italy

*This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended* ***for patients or lay persons****. A more extensive summary of its safety and clinical performance is prepared for healthcare professionals.*

*The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device*

SUMMARY

Revision History

| SSCP revision number | Data issued | Change description | Revision validated by the Notified Body |
|---|---|---|---|
| Rev. 0 | 02/2022 | First issue of SSCP according to the Technical File | Not yet.<br><br>Validation language: English. |
| Rev. 1 | 04/2022 | Revision due to the Non-Conformity | Validated<br><br>Validation language: English |

# 1. Device identification and general information

- Device trade name(s)

VISCO-SUPPLETIVE JOINT DEVICE with the following concentrations:

- 0.8% - 8 mg / 1 ml hyaluronic acid sodium salt (Mini)
- 0.8% - 16 mg / 2 ml hyaluronic acid sodium salt
- 1.6% - 32 mg / 2 ml hyaluronic acid sodium salt (Forte/Highvisc)
- 2.0 % - 50 mg / 2.5 ml hyaluronic acid sodium salt (One/Once)

Can be marketed with the following brand names:

- INTRAGEL MINI – SINOVIAL MINI – GONY ALERT MD MINI
- INTRAGEL – SINOVIAL – SINOVIAL 16 - GONY ALERT MD
- INTRAGEL FORTE – SINOVIAL FORTE – SINOVIAL 64 - GONY ALERT MD FORTE
- INTRAGEL ONE – SINOVIAL ONE – SINOVIAL 50 - GONY ALERT MD ONE - INTRAGEL ONCE – SINOVIAL ONCE – GONY ALERT MD ONCE – JOINTEX 1

- Manufacturer's name and address

The Manufacturer of this device is:
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia 2, 26900 Lodi
Italy

- Manufacturer's single registration number (SRN)

The Manufacturer's single registration number (SRN) is IT-MF-000008111

- Basic UDI-DI

The basic UDI, for this medical device, as reported in Declaration of Conformity, are the following:

- for the pre-filled syringe only is 803363895IA0034V
- for the kit is 803363895IAK0036B

- Year when the device was first CE-marked

The first certificate has been issued in 2010. At the Date of Application (DoA) of the MDR, 26th May 2021, the Medical Device "VISCO-SUPPLETIVE JOINT DEVICE" was covered by the following certificates:

- EC design-examination certificate n. EPG-0097-18, dated 26.04.2018
- Full Quality assurance system certificate n. QCT-0043-17, addendum n. 01-18 dated 26.04.2018

both issued by the Notified Body ISS (CE0373) in accordance with Directive 93/42/EEC prior to 25 May 2017 and valid until 04.06.2022.

As per MDR, Art. 120(3), starting from 26.05.2021 (DoA), the Device "VISCO-SUPPLETIVE JOINT DEVICE" is intended to be a Legacy Device, because is a Device lawfully placed on the market pursuant to Directive 93/42/EEC, which may continue to be placed on the market until 04.06.2022 (the end of the period indicated on the MDD-CE certificates).

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## 2. Intended use of the device

- Intended purpose

VISCO-SUPPLETIVE JOINT DEVICE is a medical device designed to integrate the synovial fluid, which allows restoring the physiological and rheological properties of arthritic joints and, only for 0.8%, tendons. VISCO-SUPPLETIVE JOINT DEVICE reduces pain in the joint and encourages recovery of the associated joint and, only for 0.8%, tendon mobility, acting only in the synovial cavity into which it is injected.

- Indications and intended patient groups

*INDICATION:*

VISCO-SUPPLETIVE JOINT DEVICE 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, VISCO-SUPPLETIVE JOINT DEVICE is indicated in case of pain or reduced mobility due to degenerative affections (e.g. arthrosis), post-traumatic disorders or joint and, only for 0.8%, tendon alterations (e.g. acute and chronic tendinopathy) of the large and, only for 0.8%, small joints. VISCO-SUPPLETIVE JOINT DEVICE reduces pain and restores joint and tendon mobility.

*TARGET POPULATION:*

VISCO-SUPPLETIVE JOINT DEVICE is indicated for adults of both sexes and is to be administered by intra-articular injection by qualified personnel only.

- Contraindications

VISCO-SUPPLETIVE JOINT DEVICE 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 injection site.

## 3. Device description

- Device description and material/substances in contact with patient tissues

The device VISCO-SUPPLETIVE JOINT DEVICE consists of a pre-filled syringe, containing a physiological solution of hyaluronic acid. Hyaluronic acid (HA) is a polysaccharide (a polymer composed by the aggregation of repeated identical molecules of sugar) naturally present in the human organism, and in particular it is the largest molecular component of synovial fluid, and it contributes both viscous (lubricating) and elastic (shock-absorbing) properties which are important in the lubrication and protection of cartilage. The increased friction between joint surfaces and simultaneous erosion of cartilage is determined by the development of osteoarthritis, therefore, the use of intra-articular hyaluronic acid is highly justified in order to recover the normal viscosity and protective function of synovial fluid.
Hyaluronic acid sodium salt is formed by repetitive chains of disaccharide (paired molecules of sugar) units. The length of the disaccharide chains determines its “molecular weight”. VISCO-SUPPLETIVE JOINT DEVICE is composed of high molecular weight (H-HA, constituted of “long” chains) of hyaluronic acid in a physiological solution. The high- molecular-weight of hyaluronic acid used in the device is obtained by biofermentation (produced by the fermentation of a safe bacterial strain) and have not undergone chemical modification processes; this results in excellent tolerability of the product.
It is for a single use only and the content of the syringe is sterile and pyrogen-free. The injection may only be administered by an expert healthcare professional.

- Information about medicinal substances in the device, if any

No medicinal substance is present in the device.

- Description of how the device is achieving its intended mode of action

VISCO-SUPPLETIVE JOINT DEVICE (0.8%, 1.6% and 2.0%) is a substitute for synovial fluid, which allows the re-establishment of the physiological and rheological properties of joints and tendons. In the articulation, it reduces pain and re-establishes joint and tendon mobility, acting only in the synovial cavity in which it is injected, without exerting any systemic action.
VISCO-SUPPLETIVE JOINT DEVICE 0.8% also, thanks to its lubricating and viscoelastic characteristics, acts at the level of the tendon sheath, where it improves the sliding of the tendon ("tendon gliding").

- Description of accessories, if any

No accessories are provided with the device.
The device is intended to be used with needles and it can be placed on the market as a single syringe or a system, that is in combination with other device as following:

- INTRAGEL MINI – SINOVIAL MINI – GONY ALERT MD MINI - 0.8% - 8 mg/1 ml Hyaluronic Acid Sodium Salt – available in kit of 1, 3 or 5 syringes with needle/s 21 G x ½ "
- INTRAGEL – SINOVIAL – SINOVIAL 16 - GONY ALERT MD - 0.8% - 16 mg/2 ml Hyaluronic Acid Sodium Salt – available in kit of 1, 3 or 5 syringes with needle/s 21 G x ½ "
- INTRAGEL FORTE – SINOVIAL FORTE – SINOVIAL 64 - GONY ALERT MD FORTE - 1.6% - 32 mg/2 ml Hyaluronic Acid Sodium Salt – available in kit of 1, 3 or 5 syringes with needle/s 21 G x ½ "
- INTRAGEL ONE – SINOVIAL ONE – SINOVIAL 50 - GONY ALERT MD ONE - INTRAGEL ONCE – SINOVIAL ONCE – GONY ALERT MD ONCE – JOINTEX 1 - 2.0% - 50 mg/2.5 ml Hyaluronic Acid with needle/s 21 G x ½ "

## 4. Risks and warnings

*It is very important to contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.*

- How potential risks have been controlled or managed

The Manufacturer, through expert teams have monitored all risks that could be associated to the use, design, manufacturing, product's indications, use and misuse, clinical effects and the possible adverse events. In conclusion, it is possible to state that the benefit derived from the use of VISCO-SUPPLETIVE JOINT DEVICE are higher compared to products use risks, which can be considered acceptable. In addition, the Manufacturer, continuously monitors all potential risks associated to the products, also evaluating those retrieved during the post marketing phase. Risk Assessment is systematically reviewed to ensure that VISCO-SUPPLETIVE JOINT DEVICE conforms to the progress of technology.

- Remaining risks and undesirable effects

There are some risks that are defined intrinsic, since it is impossible to eliminate or avoid. However, these remaining risks are continuously monitored by the Manufacturer through the analysis of the data obtained from the market and collection of additional data. The undesirable effects related to the injection procedure or due to the characteristics of the products are reported below.

*Side-effects*:

Extra-articular infiltration of VISCO-SUPPLETIVE JOINT DEVICE may locally cause undesirable effects. During use of VISCO-SUPPLETIVE JOINT DEVICE, 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. It is important you inform your physician/specialist about any undesirable effects occurring after the treatment.
Since the launch of the product (2005) up to 2020, VISCO-SUPPLETIVE JOINT DEVICE showed a very low incidence of adverse events taking into consideration the total adverse events collected (162) in comparison to the total patients exposed (3.211.089).
The analysis of the collected adverse events is in line with the product's profile: the majority of them are injection site reactions (pain, swelling, erythema, bruising), generally mild and transient that do not require any medication treatment and local signs or symptoms of pain and inflammation (redness, swelling, heating), that may be considered flare-ups of the underlying disorder (knee osteoarthritis) -the patients suffered from- triggered by the intra-articular injection.

- Warnings and precautions

*Contra-indications*:
VISCO-SUPPLETIVE JOINT DEVICE 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 injection site.

*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 VISCO-SUPPLETIVE JOINT DEVICE after the expiry date indicated on the package.
- Do not use VISCO-SUPPLETIVE JOINT DEVICE if the packaging is open or damaged.
- 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 VISCO-SUPPLETIVE JOINT DEVICE in the presence of heavy intra-articular effusion.
- Do not resterilise. 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, VISCO-SUPPLETIVE JOINT DEVICE must immediately be used and discarded after use.
- VISCO-SUPPLETIVE JOINT DEVICE is indicated for adult patients.
- Keep out of the reach and sight of children.
- Do not use VISCO-SUPPLETIVE JOINT DEVICE 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.

- Summary of any field safety corrective action, (FSCA including FSN) if applicable

No Field Safety Corrective Actions and Field Safety Notices have ever been issued.

## 5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

- Clinical background of the device

VISCO-SUPPLETIVE JOINT DEVICE, available in three different variants, 0.8% (1ml and 2 ml), 1.6% and 2.0% of Hyaluronic acid, is intended for the treatment of pain or reduced mobility due to degenerative diseases, conditions getting worse over the time, such as osteoarthritis, and post-traumatic diseases of the large joints.

VISCO-SUPPLETIVE JOINT DEVICE 0.8% is also used in small joints and for tendon disease, the tendinopathies. This device acts as a substitute of the liquid lubricating the joint, allowing for ease movement, named synovial fluid. The administration of this product in the intra-articular area, viscosupplementation, improves the physiological and rheological properties of joints.

Several treatment options are available for the management of osteoarthritis, although no one can cure the condition. Over the last few decades, there has been an ongoing trend to use intra-articular injections of either corticosteroids, analgesics/anti-inflammatory drugs, polymerized collagen, anti-cytokine drugs, or hyaluronic acid as alternative modalities to maximise the topical effect and minimise the systemic adverse effects [1].

Viscosupplementation is a therapeutic method by which a viscoelastic solution is injected into the intra-articular space of the joint to replace or reinforce the physic (rheological) and protective properties of the synovial fluid, decrease pain and improve joint functionality. The main benefits of viscosupplementation are attributable to its ability to restore the viscoelastic behaviour of synovial fluid in terms of joint lubrication, shock absorption, and reducing mechanical stress on the joint [2,3]. This method is commonly adopted in the orthopaedic field to treat osteoarthritis and numerous studies have investigated the efficacy of hyaluronic acid in treating the symptoms of knee osteoarthritis [4-10]. Overall conclusion is that hyaluronic acid is an effective intervention in treating knee osteoarthritis without particular adverse events [11], being recommended by the Osteoarthritis Research Society International (OARSI) guidelines [12].

Regarding the use of hyaluronic acid viscosupplementation for the treatment of tendinopathies, several studies have been performed to evaluate the efficacy of hyaluronic acid on adhesions, gliding resistance, and tendon healing [13,15-17].

After several decades of use, the safety of the administration of hyaluronic acid into the synovial cavity is generally recognised as a safe treatment [18]. It is reported that there are more than 80 marketed intra articular hyaluronic acid-based products similar to VISCO-SUPPLETIVE JOINT DEVICE preparations.
This product is on the market from several years, with a good profile of safety and effectiveness (performance). It is possible to state that non-modified (linear) hyaluronic acid for intraarticular diseases, as VISCO-SUPPLETIVE JOINT DEVICE, are widely adopted in the clinical practice and showed appreciable safety profiles.

- The clinical evidence for the CE-marking

Several clinical data have been collected on VISCO-SUPPLETIVE JOINT DEVICE, a product on the market from several years. Overall, based on the large number of clinical studies conducted, all the different concentrations of the product VISCO-SUPPLETIVE JOINT DEVICE resulted to be effective in reducing pain and restoring joint mobility in case of degenerative diseases (e.g., osteoarthritis) and post-traumatic conditions.

- 0.8% - 8 mg / 1 ml hyaluronic acid sodium salt (Mini)
- 0.8% - 16 mg / 2 ml hyaluronic acid sodium salt
- 1.6% - 32 mg / 2 ml hyaluronic acid sodium salt (Forte/Highvisc)
- 2.0 % - 50 mg / 2.5 ml hyaluronic acid sodium salt (One/Once)

*VISCO-SUPPLETIVE JOINT DEVICE 0.8% (2ml)*
VISCO-SUPPLETIVE JOINT DEVICE 0.8% resulted to be effective in reducing pain and restoring knee joint mobility in case of osteoarthritis and reduced joint mobility.
In a clinical study, VISCO-SUPPLETIVE JOINT DEVICE 0.8% was injected intra-articular, once weekly for 5 consecutive weeks; thereafter, the patients were followed-up for an additional 19 weeks with control visits. The results showed a pain improvement after 4 weeks and for stiffness and physical function after 6 weeks. This improvement continued over 24 weeks after treatment initiation and a reduction of paracetamol consumption was registered. The most frequently reported adverse event was pain and/or a burning sensation at the injection site, occurring concomitantly with or immediately after the injection. Other minor effects were reported but none of them was considered severe [19].
In another study, 40 patients with primary and secondary symptomatic knee osteoarthritis were treated with VISCO-SUPPLETIVE JOINT DEVICE 0.8%, one injection per week, for a period of 5 consecutive weeks, followed by final visit 2 weeks after the final injections. Most of both patients and the investigator judged the overall tolerance as good/excellent. The pain level assessed by the patients decreased such as rescue medication consumption was drastically reduced throughout the study period [20].
VISCO-SUPPLETIVE JOINT DEVICE 0.8%, showed similar efficacy and safety results when compared with another common intra-articular device (hyaluronic acid with chemical modification) for the treatment of knee osteoarthritis symptoms. Patients were divided in two groups and received injection of VISCO-SUPPLETIVE JOINT DEVICE 0.8%, or the other product, once weekly for 3 weeks [21].

In another study, VISCO-SUPPLETIVE JOINT DEVICE 0.8% effects and safety were also confirmed when injected twice (the second one after 2 weeks) in 17 football players affected by knee osteoarthritis.[22].
When used in the shoulder (for rotator cuff lesions or bursitis), VISCOSUPPLETIVE JOINT DEVICE 0.8% showed a great tolerability and beneficial effects, in relation the grade of cuff tears (grade I, II and IV). 100 patients with different grades of rotator cuff lesion were treated with 3 injections separated by an interval of 15 days. Overall, the treatment showed a high tolerability profile [23].

*VISCO-SUPPLETIVE JOINT DEVICE 0.8% (1ml)*

VISCO-SUPPLETIVE JOINT DEVICE 0.8% resulted to be very effective in reducing pain and improving chewing ability when injected in the temporomandibular joints, classified as small joints.
In particular, in a clinical study, 40 patients with temporomandibular joint (TMJ) degenerative disorders showed significant improvements in all outcomes (pain level, chewing efficiency, functional limitation and jaw function) and no relevant side effects were noted [24].
In another study, the cervical spine pain and function was evaluated after five sessions of viscosupplementation with VISCO-SUPPLETIVE JOINT DEVICE 0.8% (1ml) in patients with temporomandibular joint (TMJ) osteoarthritis. The results showed a significant clinical improvement in temporomandibular joint and neck pain immediately after the five sessions of VISCO-SUPPLETIVE JOINT DEVICE injection, which was maintained throughout six months after the procedure [25].
In a clinical study, the symptoms of inflammatory-degenerative temporomandibular joint (TMJ) disease were treated with 2 different hyaluronic acid-based products. Patients were divided into 2 groups treatment and who received VISCO-SUPPLETIVE JOINT DEVICE reported significant improvement in pain at chewing, mouth opening, chewing efficiency and functional limitation, whereas the improvement in pain was less significant. The results obtained during the study were comparable between two groups. No relevant adverse or side effects were observed in any patients [26].
Similar results were obtained treating 30 patients with VISCO-SUPPLETIVE JOINT DEVICE for the same disease. No side effects were observed in any patients [27].
The results reported in a clinical study [28] showed a decrease of the pain level and in increasing chewing ability elated to changes in jaw-movement speed and mouth-opening patterns after treatment with VISCO-SUPPLETIVE JOINT DEVICE 0.8% in 34 patients with temporomandibular joint (TMJ) osteoarthritis.
VISCO-SUPPLETIVE JOINT DEVICE 0.8% was also used for the carpometacarpal joint of the thumb in 44 subjects treated with two or three injections. The results showed no important differences considering pain relief and function showing that VISCO-SUPPLETIVE JOINT DEVICE 0.8% injections into the carpometacarpal joint of the thumb in osteoarthritis could be efficacious on pain and functionality as early as the first month with persistent effects at 3 months. Injections were well tolerated [29].
Similarly, VISCO-SUPPLETIVE JOINT DEVICE 0.8% was injected after 10 days after the administration of corticosteroid and compared with open surgery for the treatment of trigger finger symptoms. At 12 months, the most of patients after VISCO-SUPPLETIVE JOINT DEVICE 0.8% treatment had a complete resolution of symptoms, demonstrating that VISCO-SUPPLETIVE JOINT DEVICE injection could be considered as an alternative of surgery for the treatment of trigger finger symptoms [30].

*VISCO-SUPPLETIVE JOINT DEVICE 1,6%*

In a clinical study [31], it has been demonstrated that the concentration of VISCO-SUPPLETIVE JOINT DEVICE 1, 6%, gave beneficial effects in improving articular function, movement and pain when used in 24 obese patients with knee osteoarthritis compared to a similar product SINOVIAL HL (IBSA Farmaceutici srl 's product with high and low molecular weight of hyaluronic acid) injected in other 24 patients.

Other two clinical studies supported the beneficial effects, in terms of improvement of patient pain and joint mobility and reduction anti-inflammatory consumption, in the target hip of VISCO-SUPPLETIVE JOINT DEVICE 1,6%, when injected in 129 patients affected by symptomatic hip osteoarthritis. Only mild and local adverse event occurred [32]. Similarly, in the second study, 20 patients were treated with an intra-articular injection of VISCO-SUPPLETIVE JOINT DEVICE 1,6%, at baseline and after 40 days. Pain evaluation decreased significantly after 6 and 12 months, the disability was also reduced. Consumption of anti-inflammatory drugs was reduced as well in most of patients. Two patients complained side effects that disappeared less than 3 hours later [33].

Finally, VISCO-SUPPLETIVE JOINT DEVICE 1,6% proved to be effective in terms of pain relief, functional improvement and bleeding rate when used in patients with hematologic disease with knee and ankle ostearthirtis [34]. In another study, subjects with knee osteoarthritis received, after a weekly injection of VISCO-SUPPLETIVE JOINT DEVICE 1,6% for 3 weeks, a single injection VISCO-SUPPLETIVE JOINT DEVICE 2% at 4-month interval (4, 8 and 12 months). This schedule provides persistent positive results in terms of reduced pain, improved function, and reduction of non-steroidal anti-inflammatory drug consumption [35].

*VISCO-SUPPLETIVE JOINT DEVICE 2%*

The positive effects in pain and function with the injection of hyaluronic acid in the osteoarthritis disease were confirmed also for the variant VISCO-SUPPLETIVE JOINT DEVICE 2% if injected with a single injection in 21 patients with symptomatic knee osteoarthritis. The benefit in reduction of pain and improvement in the mobility were recorded in all patients with different severity of the disease up to 120 days after the treatment. The treatment was well tolerated in all patients [36]. Similar results were obtained after single hip injection of VISCO-SUPPLETIVE JOINT DEVICE 2% [37].

Overall, the above-mentioned studies confirmed that all the VISCO-SUPPLETIVE JOINT DEVICE concentrations are effective when injected in small and large joints. The product injection was considered safe and overall, well tolerated.

Therefore, all clinical studies conducted by experts demonstrated that all VISCOSUPPLETIVE JOINT DEVICE concentrations, as well as hyaluronic acid intra-articular injections, are effective treatments in reducing pain and restoring joint and tendon mobility, demonstrating the treatment is beneficial to patients.

- Safety

  Several studies have been conducted with each variant of the device, in order to support the claims, the beneficial effects and the safety profile. VISCO-SUPPLETIVE JOINT DEVICE resulted to be effective in reducing pain and restoring joint and tendon mobility, demonstrating that the treatment is beneficial to patients.

Data collected on injections of hyaluronic acid demonstrated the safety and the good tolerability of VISCO-SUPPLETIVE JOINT DEVICE when injected according to indication. No severe or relevant treatment-related side effects were enregistered in all the analysed studies.
Moreover, no cases of severe allergic or anaphylactic reactions were observed in any study conducted on the device. No significant adverse effects were reported, and no injection-site ecchymosis or hematomas have been reported.
Hyaluronic acid has many advantages when compared to other products: it has a low risk of allergic and immunogenic reactions, and it possesses viscoelastic properties allowing easy injection.
The safety profile is also enhanced because the hyaluronic acid contained in VISCO-SUPPLETIVE JOINT DEVICE is obtained through fermentation by bacteria, without any other chemical modifications, with a very safety profile.
The Manufacturer keeps collecting data through analysis from the market and clinical studies for monitoring the safety and the performance of the products, in relation to the indications of use reported in the leaflets.

This product is on the market from several years, with a good profile of safety and performance. It is possible to state that the VISCO-SUPPLETIVE JOINT DEVICE as in general injections of hyaluronic acid for intraarticular diseases are widely adopted in the clinical practice and showed appreciable safety profiles.

## 6. Possible diagnostic or therapeutic alternatives

- General description of therapeutic alternatives

Osteoarthritis occurs when the cartilage cushioning the ends of bones in joints gradually deteriorates. Different treatment options are available to manage pain and reduced mobility caused by this disease, although no one can cure the condition. The choices of the better strategy to manage symptoms are relative to different factors such as the severity of the disease and the type of articulation.
Less invasive therapies such as aerobic exercise, self-management programs, weight loss, shock-absorbing footwear and oral drugs (analgesics such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDS)) are the preferred management methods in cases of the disease is in the first steps of severity. These treatments help to relieve symptoms and improve function.
Treatments such as exercise and weight loss often help to reduce the pain however it is often necessary to take pharmacologic analgesics in parallel [14].
Once the disease is in progress, treatment options chosen are intra-articular injections and surgery (joint arthroplasty) . This latter treatment is used in the end-stage of the disease when no other procedures or therapies have been efficient.
About the treatment for tendon injuries (tendinopathies), no gold standard for the management of this clinical condition is documented, due the controversial clinical results between various studies conducted during the last few years . The list of currently available interventions for tendinopathy include surgery,

nonsteroidal anti-inflammatory drugs, corticosteroids, shockwave therapy, and the injection of a lot of type of substances in the tendon area such as platelet-rich plasma injection . Additionally, peritendinous injections of hyaluronic acid (HA), viscosupplementation, seems to be an effective experimental therapeutic option for the management of chronic tendinopathy. .

However, it is recommended to contact your healthcare professional to consider alternative treatments in accordance with your individual situation.

## 7. Suggested training for users

The products must be injected by expert healthcare professional.
The Manufacturer IBSA Farmaceutici Italia srl continuously plans and performs training dedicated to injectors.

## 8. References

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