VIJOINT

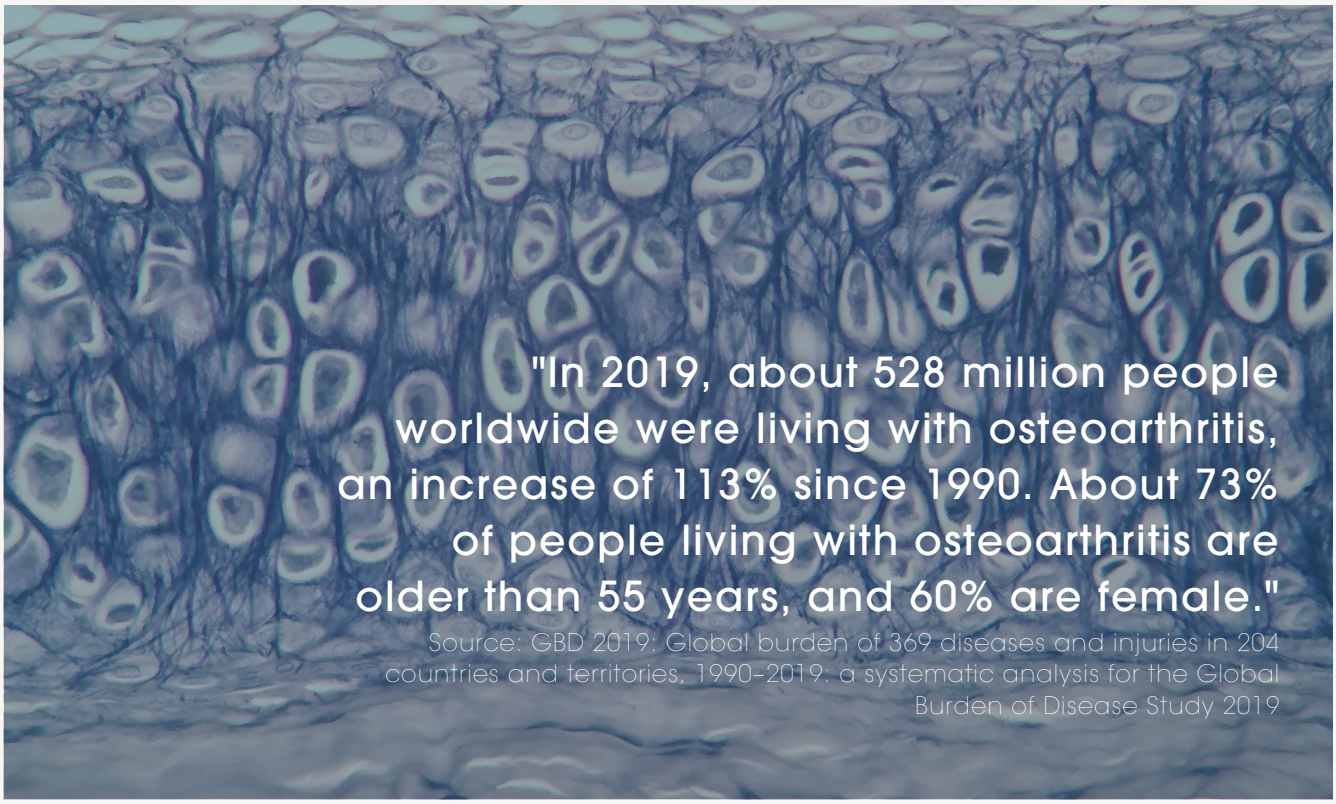
Medical Device Class III

the most complete line for the viscosupplementation

Biofarma group

VIJOINT

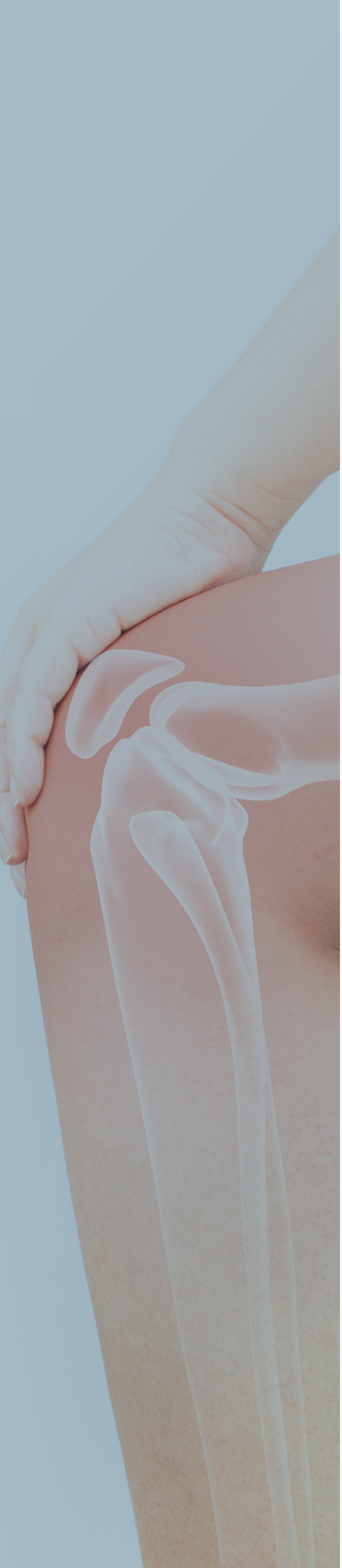
A MEDICAL DEVICE FOR THE TREATMENT OF OSTEOARTRITIS



VIJOINT IS A HYALURONIC ACID SODIUM SALT BASED MEDICAL DEVICE PRESENTING ITSELF AS SINGLE-USE STERILE PRE-FILLED SYRINGES FOR INTRA-ARTICULAR INJECTION.

Currently, there are no real treatments for osteoarthritis, the remedies that are applied can only manage the symptoms and in particular relieve pain. These include pharmacological and non-pharmacological solutions and these can be used in a complementary or alternative way.

In this context, viscosupplementation with injections of Hyaluronic Acid Sodium Salt emerges as an important ally in alleviating the symptoms of OA and slowing its progression. In this sense, Vijoint, the product developed by Biofarma Group's research and development laboratories, represents a valid example on the market.



PRODUCT BACKGROUND

Osteoarthritis is a degenerative joint condition. It causes pain, swelling and stiffness, affecting a person's ability to move freely.

Osteoarthritis affects the entire joint, including the tissues around it. It is most common in the knees, hips, spine and hands.

Many factors can contribute to developing osteoarthritis. Some include a history of joint injury or overuse, older age and being overweight. It affects women more than men.

Exercise and healthy eating to build strong muscles and keep a healthy weight can reduce symptoms. Surgery to replace joints is used in severe cases to reduce pain and regain mobility.

Once pain and loss of movement function become chronic, people with osteoarthritis often experience restrictions in participating in meaningful activities, decreased well-being, and psychological distress.

Source: World Health Organization

PRODUCT DESCRIPTION

Vijoint is a synovial fluid replacement for patients affected by degenerative or mechanical arthropathy which causes pain or reduced mobility.

PHARMACEUTICAL FORM

A glass syringe containing 2 ml of saline solution or 3 ml of saline solution. The syringe content is steam sterilised.

MECHANISM

The Vijoint medical device is a substitute of the synovial liquid in virtue of its Hyaluronic Acid Sodium Salt content; because of this, it finds application in the visco-supplementation therapy of joints suffering from degenerative or mechanical arthropathy which leads to pain or reduced mobility. The device mechanism of action is finalized to the synovial liquid recovering by the intraarticular injection of Hyaluronic Acid Sodium Salt which acts as lubricant and shock-absorber for joints and ligaments. The device only acts at the joint level without any systemic action. The device mechanism of action is to restore the synovial fluid as this is formed by glycosaminoglycans.

HOW TO TAKE

Vijoint must be administered one single time per therapy; if necessary, injection can be repeated according to the concentration used after one week for 3 to 5 consecutive weeks

TARGET

People suffering from osteoarthritis

SHELF LIFE

36 months

PACKAGING AVAILABLE

Pre-filled ready-for-use syringes in single blister packs

TYPES OF VIJOINT

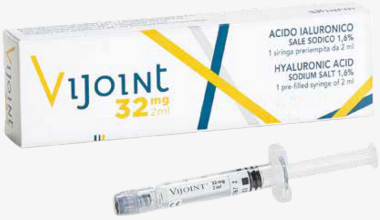
Vijoint device is available in four variants that differ for Hyaluronic Acid Sodium Salt content. The four variants share the same intended use and manufacturing process, have the same qualitative formulation and comparable quantitative formulation. Three variants are packaged in 2 mL syringes while one variant is packaged in a 3 mL syringe.

Vijoint medical device includes the following variants:

- 0.8% concentration of HA Sodium Salt in syringe of 2ml; pack contains 1, 3 or 5 syringes;
- 1.6% concentration of HA Sodium Salt in syringe of 2ml; pack contains 1 or 3 syringes;
- 2.0% concentration of HA Sodium Salt in syringe of 2ml; pack contains of 1 or 3 syringes;
- 2.0% concentration of HA Sodium Salt in syringe of 3ml; pack contains of 1 or 3 syringes;

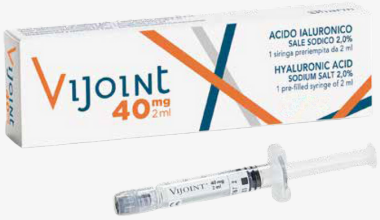
16 mg/2ml

Hyaluronic Acid Sodium Salt 0,8%



32 mg/2ml

Hyaluronic Acid Sodium Salt 1,6%



40 mg/2ml

Hyaluronic Acid Sodium Salt 2,0%

60 mg/3ml

Hyaluronic Acid Sodium Salt 2,0%

KEY INGREDIENTS

Hyaluronic Acid Sodium Salt

Hyaluronic Acid Sodium Salt is a natural polysaccharide present in numerous human tissues, especially in synovial fluid, and acts on joints both as a cartilage and ligament lubricant and as a shock absorber. Many studies have shown that the injection of Hyaluronic Acid Sodium Salt into joints affected by osteoarthritis restores synovial fluid viscosity and elasticity, with a consequent reduction in pain and improvement in the joint's mobility.

VERSION	INGREDIENTS	INGREDIENTS	CONCENTRATION
V1	Hyaluronic Acid Sodium Salt*	16 mg	0,8%
V2	Hyaluronic Acid Sodium Salt*	32 mg	1,6%
V3	Hyaluronic Acid Sodium Salt*	40 mg	2%
V4	Hyaluronic Acid Sodium Salt*	60 mg	2%

*in syringe of 2 ml

SCIENTIFIC EVIDENCE and PROPRIETARY STUDIES

This survey is an investigation regarding surgeries where was used. The survey was conducted by orthopaedic surgeons who demonstrated to use Vijoint in their normal practice, involving a cohort of patients needing anyway synovial fluid replacement for their own clinical conditions. The survey was run via a paper questionnaire completed by the surgeons immediately before and after the surgical practise and during the follow-up control, conducted according to the surgeon's decisions, at any time after surgery within a maximum period of 4 weeks (+/-7days).

Questionnaire distribution

The questionnaires were distributed to six orthopaedics, working in Italian settings, to gain clinical data on the real-world scenarios in which this medical device was used together with its performance and safety.

Statistical analysis

This survey involving 43 knee infiltrations with Vijoint confirms the safety and tolerability of this MD, confirms its usability within the scope of the intended use and confirms the performance. No previously unidentified or unknown side-effects or contraindications related to Vijoint or to its use emerged from this survey and no emergent risk was identified.

Results

Results are summarized using descriptive statistics. Binary, categorical, and ordinal parameters, including adverse reactions were summarized by means of absolute number and/or percentage.

Orthopaedic surgeons involved in the observations

Six Italian orthopaedic surgeons took part in this PMCF (Post Market Clinical Follow up), distributed, in one or more clinics, in 9 cities in 4 different Italian regions. They performed a total of 43 intra-articular infiltrations, which were the target of observations reported in this PMCF.

SCIENTIFIC EVIDENCE and PROPRIETARY STUDIES

Partecipants:

Twenty-five (25) right knees (58.1%) and 18 left knees (41.9%) were subjected to intra-articular infiltrations involving 17 female subjects (39.5%) and 26 male subjects (60.5%), respectively of the average age of 68.2 years (range 48-87) and 67.3 years (range 34-82).

Duration:

This survey was carried out over about two months, between 19 December 2022 (first observation made) and 16 February 2023 (last observation made). The gap between the first and second series of observations (baseline, before intervention, and follow-up) of the same knee was on average 3.9 weeks, with a minimum of 1.1 weeks and a maximum of 5.0.

Conclusions:

- This survey involving 43 knee infiltrations with Vijoint confirms the safety and tolerability of this MD, confirms its usability within the scope of the intended use and confirms the performance.
- No previously unidentified or unknown side-effects or contraindications related to Vijoint or to its use emerged from this survey and no emergent risk was identified.

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