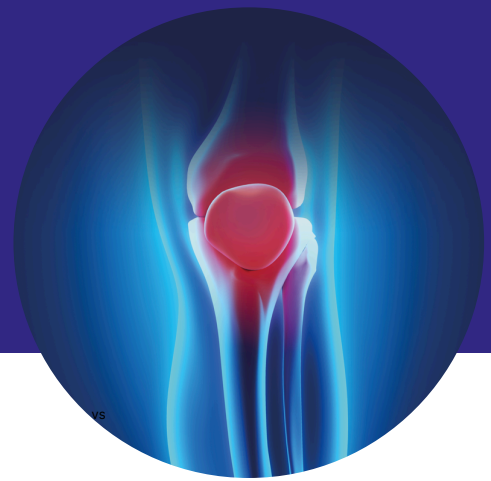


## IMPLANT CARD

### PATIENT INFORMATION LEAFLET



## Product

<b>Brand name</b>	KioMedine <sup>vs one</sup>
<b>Legal Manufacturer</b>	 KiOmed Pharma <a href="http://www.kiomedpharma.com">www.kiomedpharma.com</a>

## What is KioMedine<sup>vs one</sup>?

KioMedine<sup>vs one</sup> is a sterile liquid implant intended for synovial fluid supplementation and classed as a medical device.

KioMedine<sup>vs one</sup> is used to **relieve symptoms related to osteoarthritis of the knee**, such as pain, **in adults aged 18 years and above**.

KioMedine<sup>vs one</sup> works by providing lubrication, reducing friction in the joint and protecting synovial polymer from being broken down.

KioMedine<sup>vs one</sup> is injected directly into the knee joint by a doctor/healthcare professional experienced in intra-articular injections.

KioMedine<sup>vs one</sup> is made of 60 mg of a chitosan derivative, 105 mg of sorbitol, and phosphate-buffered water for injection.

The 3 mL volume of KioMedine<sup>vs one</sup> is suitable for an injection into one knee.

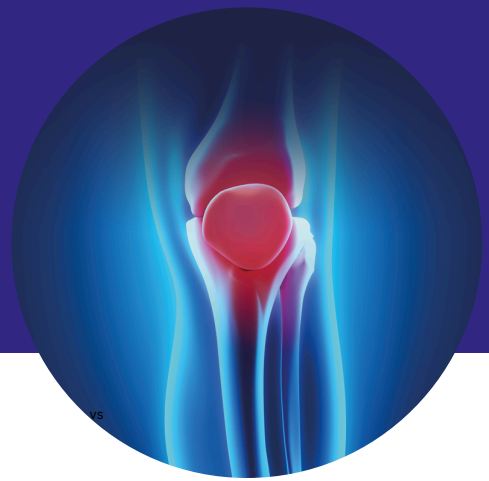
## Warnings

### You must not receive KioMedine<sup>vs one</sup> if:

- You have had an allergic reaction to any of the ingredients. KioMedine<sup>vs one</sup> is derived from polysaccharides of edible mushrooms and should not be injected in patients with related allergies.
- You have an infection or a skin disease at or around the injection site (area of the knee).
- You suffer from severe inflammation, synovitis (inflammation of the knee joint) or inflammatory arthritis of the knee joint.
- You have a history of autoimmune diseases or gout (or other crystal diseases)
- You suffer from lymphatic or venous stasis or serious blood disorders.
- You are pregnant or breastfeeding.
- You are under 18 years of age.

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## Precautions to take after the injection

You may walk normally.

Avoid any intense physical activity or carrying heavy loads for 48 hours after the injection.

Use the knee treated “gradually” and do regular physical exercise.

Exercise is important to maintain joint health and flexibility, and even to slow the progression of osteoarthritis. It also helps strengthen the muscles supporting your knee.

The presence of KiOmedine<sup>vs one</sup> may affect the interpretation of MRI imaging (darker spots) for one day after the injection.

## Possible side effects

### Most common side effects:

- joint pain, stiffness, and swelling,
- pain or reactions at the injections site,
- reduced mobility and
- buildup of fluid in the knee (effusion).

These effects are temporary but can last from 1 day to 1 week, and may affect your daily activities. However, they can be managed with rest, cold application, pressure bandage, oral painkillers (such as paracetamol), and/or non-steroidal anti-inflammatory drugs (such as ibuprofen).

### Less common side effects:

- synovitis (inflammation of the synovial membrane of a joint), inflammation,
- rash, itching, mild allergic reaction,
- low-grade fever,
- generally feeling unwell, or
- inability to fully move a joint (joint lock), difficulty to walk.

### Other possible side effects:

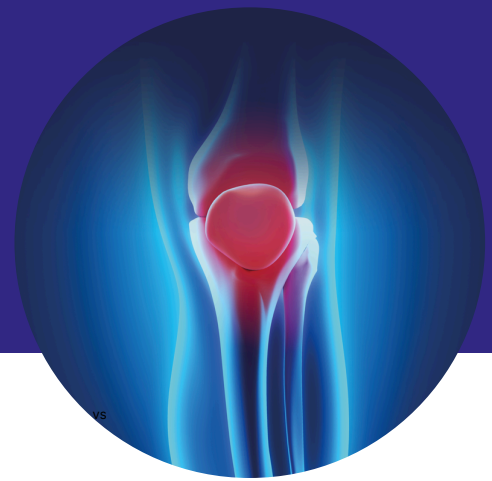
- Local reactions: infection, inflammation of the small sacs of fluid that cushion the knee joint (bursitis), joint warmth, cracking of the knee, joint diseases (arthropathy), worsening of the osteoarthritis, leakage of fluid (discharge).
- Distant reactions: muscle cramps or spasms, flushing, chills, nausea, headache, low or high blood pressure, back pain, pain or swelling in lower legs or hands.

**If the side effects persist for over 1 week or worsen significantly after the injection, you should contact your doctor.**

You can report any serious incident related to the injection to [vigilance-rheumatology@kiomedpharma.com](mailto:vigilance-rheumatology@kiomedpharma.com) or to your local health authorities.

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### Expected lifetime of the product?

KioMedine<sup>vs one</sup> is a temporary implant.

Once injected, KioMedine<sup>vs one</sup> will break down into non-toxic parts and in about one month will be absorbed by the body. After this period, the product will not be present anymore, but you may feel positive effects up to 6 months.

The treatment may then be repeated according to your doctor's recommendation.

### Information about the implant card

After your injection, you will receive an implant card completed by the health care professional who performed the injection. The purpose of the implant card is to:

- enable the identification of the injected device and get access to other information related to the injected device
- allow you to contact the health care professional if necessary

**KioMedine<sup>vs one</sup> EUROPEAN IMPLANT CARD**

UNIQUE FLUID IMPLANT FOR OSTEOARTHRITIS TREATMENT

(1) \_\_\_\_\_

(2) \_\_\_\_\_

(3) \_\_\_\_\_

<https://www.kiomedine-one.com/patients>

EN intraarticular fluid implant / FR Implant intraarticulaire liquide / DE Intraartikuläres Flüssigimplantat / ES Implante líquido intraarticular / PT Implante líquido intra-articular / IT Impianto fluido intra-articolare / EL Εμφύτευμα ενδοαρθρικού υγρού / TR Intraartiküler sıvı implant / RO Implant fluid intraarticulară / NL Intra-articulair vloeibaar implantaat / HU Intraartikuláris folyadék implantátum / PL Płynny implant dostawowy

(4)  
Place one of the peelable labels affixed on the paper lid here

KiOmed Pharma  
Rue Haute Claire, 4  
4040 Herstal, Belgium

UDI-DI: 0540402351400 4

Symbol	Description
	Name of the patient
	Date of the injection
	Name and address of the healthcare institution or doctor who performed the injection
	Website where the patient can obtain additional information on the product
	Name of the product (MD = Medical Device)
	Lot number of the injected product
	European reference number of the product (UDI = Unique Device Identifier)
	Name and address of the legal manufacturer of the product

Version 3 of the patient information leaflet issued in November 2024.

Manufacturer: KiOmed Pharma SA