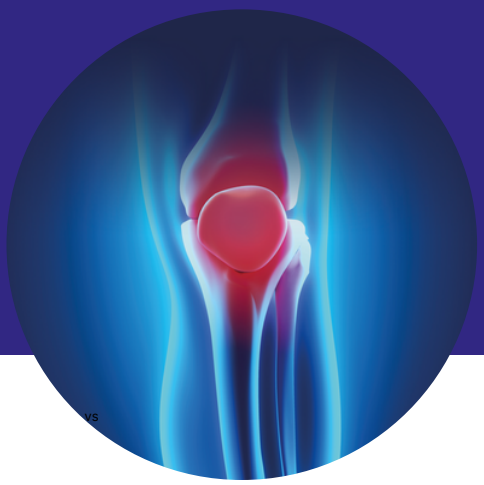
KioMedine vs one

IMPLANT CARD

PATIENT INFORMATION LEAFLET



Product

Brand name	KioMedine^{vs}one
Legal Manufacturer	KiOmed Pharma www.kiomedpharma.com

What is KioMedine^{vs}one?

The medical device, KioMedine^{vs}one, is for synovial fluid supplementation.

KioMedine^{vs}one is meant to relief symptoms related to osteoarthritis of the knee, such as pain, by providing lubrication, reducing friction in the joint and protecting synovial polymer from degradation.

KioMedine^{vs}one must be injected only by an authorized physician experienced in intra-articular injections in adults suffering from painful knee affected by osteoarthritis.

KioMedine^{vs}one is a sterile medical device made of 60 mg of a chitosan derivative, 35 mg of sorbitol, and phosphate-buffered water for injection.

You should not receive KioMedine^{vs}one if:

- You suffer from known allergy or hypersensitivity to the product components.
- You have infections or skin disease at or around the injection site (area of the knee).
- You suffer from severe inflammation, synovitis or inflammatory arthritis of the knee joint.
- You have a history of autoimmune or crystal diseases (such as gout and calcium pyrophosphate deposition (CPPD)).
- You suffer from lymphatic or venous stasis or serious blood disorders.
- You are pregnant or a lactating woman
- Not an adult (above 18 years old).

Which precautions do you need to take after the injection?

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

After the injection, we recommend that you use the knee treated “gradually” and to do regular physical exercise.

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

The presence of KioMedine^{vs}one may create local MRI artefacts for one day after the injection.

KiOmed PHARMA

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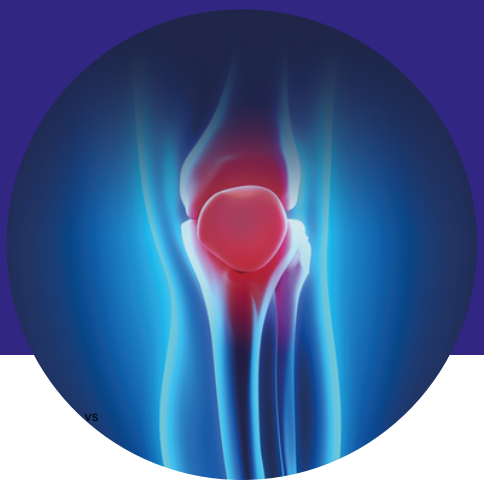

What are the possible side effects?

As with all intra-articular injections, the most frequent side effects include pain, stiffness, swelling, reduced mobility and effusion of the knee.

These side effects are temporary but can last from few days to few weeks. They may impact 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 frequent side effects following the injection include synovitis (inflammation of the synovial membrane of a joint), inflammation, rash, itching, mild allergic reaction, low-grade fever, hypotension, dizziness, malaise, difficulty to walk.

Other side effects may occur such as :

- Infection
- Local reactions: bursitis, joint warmth, locking or cracking of the joint, joint diseases (arthropathy), complication of the osteoarthritis (pseudoseptic arthritis, anaphylactic arthritis, aggravated osteoarthritis), leakage of fluid.
- Distant reactions: muscle cramps or spams, bruising, flushing, chills, urticaria, nausea, headache, hypertension, back pain, pain in extremities, swelling in lower legs or hands

If the side effects persist for over one week or worsen significantly after the injection, you should contact your physician.

You can report any serious incident related to the injection to vigilance-rheumatology@kiomedpharma.com or to your local health authorities.

What is the expected lifetime of the device?

KioMedine[vs]one is a temporary implant.

Once injected, KioMedine[vs]one will degrade in about one month. After this period, the product will not be present anymore.

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
- get access to general information related to device
- allow you to contact the health care professional if necessary

KiOmed PHARMA

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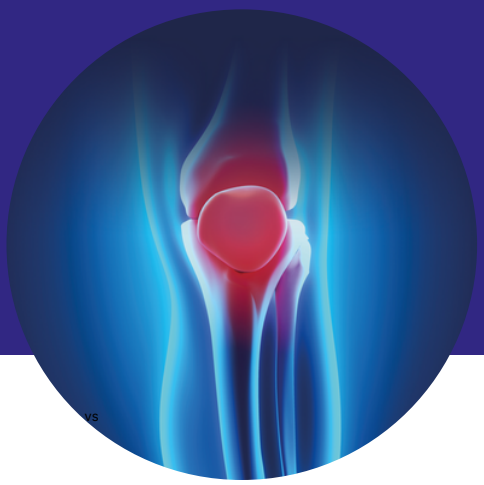

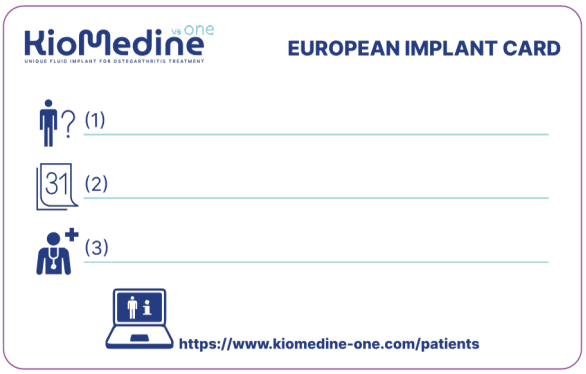

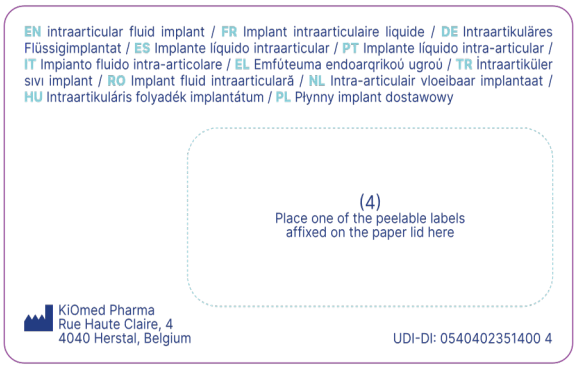

Symbol	Description
	Name of the patient
	Date of the injection
	Name and address of the healthcare institution or doctor who performed the injection
	Website where the patient can obtain additional information on the product
MD	Name of the product (MD = Medical Device)
LOT	Lot number of the injected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

This is version 1 of the patient information leaflet issued in August 2024