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Patient Information Leaflet

This leaflet contains information about your implant. It does not contain all the information and if you have any questions, ask your healthcare team. All implants have risks and benefits. Follow your healthcare team's recommendations even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

Implant Description

Cellular Matrix BCT-HA is used for preparation of autologous[1] platelet-rich plasma (PRP), from venous blood, combined with **hyaluronic acid (HA)**.

The resulting PRP/HA combination is used for intra-articular injections into your knee, to reduce pain symptoms and to improve its mobility. The intra-articular injection should be performed by a qualified physician.

[1] *Autologous: refers to a tissue or cells originating from your own body and administered to yourself.*

Implant Material

Your implant contains the following substances:

- 2 ml of hyaluronic acid gel
- 0,6 ml of anticoagulant solution, in liquid form (4% sodium citrate solution)

These products are combined with platelet-rich plasma (PRP) that is prepared from your own blood by your physician, just before its use.

Information for Safe Use

Make sure you follow your physician's recommendations after the treatment.

Not following your physician's advice(s) may result in complications and the need for additional medical procedures.

Discuss any questions, concerns, or potential side effects with your physician.

Contraindications

Absolute contraindications:

- Platelet dysfunction syndrome
- Critical thrombocytopenia
- Hemodynamic instability
- Severe metabolic or systemic disorders
- Septicemia
- Acute/local infection at the site of the procedure
- Patient unwilling to accept risks
- Hypersensitivity (allergy) to one of the components (including HA)

Relative contraindications:

- Consistent use of NSAIDs[2] within 48 hours before the procedure
- Consistent use of other medication(s) or dietary supplement(s) which alter platelet function, within 3 days before the procedure
- Corticosteroid injection at the treatment site within 1 month before the procedure
- Systemic use of corticosteroids within 2 weeks before the procedure
- Tobacco use
- Recent fever or illness
- Malignant diseases, especially those affecting blood, bone marrow or bones, and cancers in metastatic phase
- Autoimmune diseases with presence of antibodies and progressive (Hashimoto, rheumatoid arthritis, lupus, etc.)
- Impaired coagulation
- Hemoglobin count < 10 g/dl
- Platelet count < 10^5/ µl

[2] *NSAIDS : Non-steroidal anti-inflammatory drugs.*

Precautions

Injections of the PRP/HA combination into the joint cavity must be performed by a qualified physician with the same precautions as any other intra-articular injection, and preferably using ultrasound guidance. Joint effusion, if present, should be removed before injecting the PRP/HA combination. The physician must evaluate the physical aspect of the collected fluid. If any doubt, appropriate measures should be undertaken, and the physician must assess whether the intra-articular injection of PRP/HA should be performed or not.

Following intra-articular injection, you must rest for 1h after the injection (no physical activity) and avoid prolonged (no more than 10 minutes) standing or walking for the first 12 hours after the intra-articular injection.

Possible Side Effects / Risks

Your physician will provide information about the possible side effects of your medical procedure. All medical procedures have risks.

Blood collection may cause damage to the blood vessels, hematomas, superficial phlebitis, early or late infection and/or temporary or permanent nerve damage that may result in pain or numbness.

Following intra-articular injections, local secondary inflammatory reactions may occur at the site of injection. This may result in temporary pain, feeling of heat, redness and swelling in the joint area treated with the PRP/HA preparation. Use of ice packs in the minutes following the injection, or oral analgesic treatment (acetaminophen) the day following the injection may reduce these effects. The intake of non-steroidal anti-inflammatory drugs (NSAID) must be avoided.

Following injection with HA, there have also been occasional reports of hyper-sensitivity (allergy), including, rarely, anaphylaxis[3]. The administration of HA was also reported to provoke pronounced inflammatory reactions. Injection may lead to infection if general precautions for injection and asepsis are not respected.

[3] *Anaphylaxis*: *refers to a severe state characterized by a drop of blood pressure, collapse, loss of consciousness and shock.*

NB: In case any serious incident occurs in relation to the device, the physician and/or yourself should report this incident to the manufacturer and the competent authority of the Member State in which the physician and/or yourself is established.

These risks may require additional treatments. This list does not include all risks. Your physician can further explain the risks of your intervention.

Expected Implant Lifetime and Follow Up

The hyaluronic acid in the PRP/HA combination is a resorbable implant. Following injection, the resorption time of hyaluronic acid is less than 30 days.

Information specific to your implant, such as lot number and unique device identifier (UDI), are located in the patient records kept by your healthcare provider. This information is also located on your Patient Implant Card transmitted by your healthcare provider after the implant procedure, which you must keep for at least 30 days.

Reporting Adverse Effects

If you wish to report any adverse effects that you believe are a result of your implant, please speak with your physician/medical team or report the information to Regen Lab SA, Switzerland at pms@regenlab.com

Medical Device:

Cellular Matrix BCT-HA Kit (Ref: BCT-HA-1 / Ref: BCT-HA-3)

Manufacturer:

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