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

ArthroVisc®40 syringes contain hyaluronic acid gel for intra-articular injections for symptomatic treatment of pain and mobility improvement in knee osteoarthritis.

The injection of ArthroVisc®40 must be performed by a physician qualified for intra-articular injections.

Implant Material

Your implant contains 2 ml of hyaluronic acid gel.

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

The product must not be administered if you present an ascertained hypersensitivity (allergy) to one of the components or if you suffer from serious disease such as infection in joint or acute/local infection on the site of the procedure.

Precautions

Injections into the joint cavity must be performed with the same precautions as any other intra-articular injection, and if necessary, using imaging control.

You must respect a delay of 1h without physical activity after the injection and avoid strenuous or weight bearing activities for 48 hours following the intra-articular injection.

Possible Side Effects / Risks

Injection may cause damage of the blood vessels and hematomas. Local secondary inflammatory reactions may occur at the site of injection. This may result in phenomena such as temporary pain, feeling of heat, redness and swelling in the treated joint.
There have also been occasional reports of hyper-sensitivity, including, rarely, anaphylaxis[1].
Ice-packs application in the minutes following the injection, or local analgesic treatment the day following the injection may decrease these inconveniences.

[1] *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 gel 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 Events

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:

ArthroVisc® 40 Kit (Ref: ARV-HA40-1 / Ref: ARV-HA40-3)

Manufacturer:

Regen Lab SA
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