

Patient Information Leaflet for ArthroVisc40 Kits

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.

The name and reference of the product that was implanted can be found on your implant card. If healthcare professionals ask about your implant, please show them your implant card.

Implant Description

ArthroVisc40 syringes contain hyaluronic acid gel for intra-articular injections into the knee for symptomatic treatment of articular pain and mobility improvement. The injection of ArthroVisc40 must be performed by a physician qualified for intra-articular injections.

Implant Material

Your implant contains a hyaluronic acid gel.

Information for Safe Use

Make sure you follow your doctor's recommendations after the treatment. Not following your doctor's advice may result in complications and the need for additional medical procedures.

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

Contraindications

Do not administer to patients with ascertained hypersensitivity to one of the components or suffering from serious disease such as infection in joint or acute/local infection on the site of the procedure.

Warnings/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. The patient 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

Your doctor will provide information about the possible side effects of your medical procedure. All medical procedures have 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. Ice-packs application in the minutes following the injection, or local analgesic treatment the day following the injection may decrease these inconveniences.

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, are included on the implant card. This information is also located in the patient records kept by your healthcare provider.

Reporting Adverse Effects

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

Manufacturer

Regen Lab SA, En Budron B2, 1052 Le Mont-sur-Lausanne , Switzerland

EC REP

Regen Lab France S.A.S, 2 Avenue de Laponie, 91940 Les Ulis, France

List of kits:

- ArthroVisc40 Kits, Ref: ARV-HA40-3 & ARV-HA40-1