**Instructions for use** **[EN]**

# LIPOTRIS™

**Liposomal intra-articular composite gel, 2 ml**

**Composition**
Each 1 ml contains:

| | |
|---|---|
| Sodium hyaluronate | 22.000 mg |
| 1-palmitoyl-2-oleoyl-phosphatidylcholine (POPC) | 0.800 mg |
| Sodium chloride | 9.060 mg |
| Disodium hydrogen phosphate, anhydrous | 0.241 mg |
| Sodium dihydrogen phosphate dihydrate | 0.047 mg |
| Water for injection | q.s. |

**Description**
Lipotris™ is a liposomal composite gel for intra-articular application, developed on the basis of hyaluronic acid and liposomes. The hyaluronic acid content is obtained by bacterial fermentation and the liposomes are formed from 1-palmitoyl-2-oleoyl-phosphatidylcholine (POPC) of synthetic origin. The two components of the formulation are able to interact with each other to form a composite material – a material with unique tribological properties. The medical device is sterile and non-pyrogenic.

**Indications**
Pain and decreased articular mobility associated with traumatic or degenerative changes including osteoarthritis.

**Contraindications**
The medical device should not be used in patients:
- with known hypersensitivity to any of the components of the product;
- with septic arthritis;
- with dermatosis at the injection site;
- taking anticoagulants.

**Precautions**
All safety precautions during procedure should be taken to prevent occurrence of septic arthritis.
Medical device intended only for intra-articular injections.
Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation as hyaluronan can precipitate in their presence.
Children, pregnant or nursing women should not be treated with this medical device as there are no clinical data available on its use in these patients.
Medical device should not be used if a pre-filled syringe is damaged.
Medical device must be used before the expiration date indicated on the packaging.
Do not resterilise.
The pre-filled syringe is intended for single-use only.
Store at temperature between +2°C and +25°C. Keep away from sunlight. Protect from moisture.
Medical device must be kept out of the reach of children.

**Potential side effects**
Biocompatibility studies have confirmed the high safety of the medical device. Transient local reactions such as pain, redness and swelling may occur after intra-articular injection. These effects can be reduced by cooling the injection site for 5 to 10 minutes after the injection. Simultaneous oral intake of analgesics and anti-inflammatory drugs (NSAIDs) may be beneficial for pain relief.

**Serious adverse events reporting**
In case of serious adverse events, it should be reported to the manufacturer and to the Member State competent authority. By reporting adverse events, more information on safety of the medical device can be gathered.

**Interactions**
No data.

**Administration and dosage**
Disinfect the skin at the site of the planned injection. Take the pre-filled syringe from the blister, unscrew the Luer-lock closure and screw a suitable sterile needle onto the syringe. Remove air bubbles before injection. After injection, place the used syringe in a medical waste container and dispose of it.
In case of intra-articular effusion, it is recommended to remove it before the administration of the device.
The therapy consists of a series of three intra-articular injections, administered at weekly intervals. The beneficial effects of the treatment last for at least six months. The treatment cycle may be repeated, if required.

**Properties and mode of action**
The composition of Lipotris™ takes advantage of the fact that hyaluronic acid with its precisely selected properties is able to interact closely with liposomes formed from phospholipids and form a uniform liposomal intra-articular composite gel – Lipotris™. When administered into the joint, Lipotris™ actively forms a boundary layer on the cartilage surface via a dedicated protein, lubricin. The Lipotris™ mechanism of action involves the transformation of the type of movement between cartilaginous surfaces from sliding to rolling, thereby enabling the creation of surfaces with extremely reduced friction.

Due to its unique mechanism of action, Lipotris™, when administered intra-articularly, provides accelerated clinical functionality in reducing pain, as well as increased mobility of the joint affected by traumatic or degenerative changes.

**Package**
Pre-filled syringe with gel placed in a blister, instructions for use, implant card, patient-doctor stickers, sterile 21G needle.

CE 0318 **Needle manufacturer:**
Becton Dickinson S.A.
Carretera de Mequinenza, s/n, 22520 Fraga (Huesca), Spain

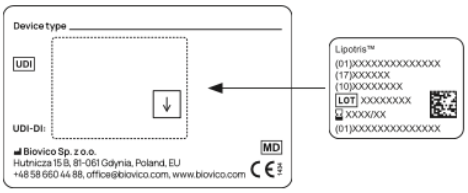
**The needle is sterilized with ethylene oxide.**

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
| | Manufacturer | CE | CE marking of conformity |
| | Keep away from sunlight | LOT | Lot number |
| | Keep dry | | Expiry date |

**2. GENERAL PRINCIPLES**
- All fields must be completed legibly.
- Product identification information (name, lot number, UDI, expiry date) is affixed by means of a manufacturer's sticker.
- The remaining fields shall be completed by the medical staff after implantation.

**3. INSTRUCTIONS – PRODUCT SIDE**
To be completed by medical staff after implantation.
- **Device type** – insert "Liposomal intra-articular composite gel".

Place one of the three stickers supplied with the product containing product identification data in the designated space:
- product name;
- unique device identifier (UDI);
- UDI device identifier (UDI-DI);
- lot number;
- expiry date.




**4. INSTRUCTIONS – PATIENT SIDE**
To be completed by medical staff after implantation. All fields must be completed legibly, preferably in block capitals.

- enter the patient's full name or patient ID number.
- enter the date of procedure (DD-MM-YYYY).
- enter the name and address of the facility and the name of the physician performing the implantation.




**5. CONTROL AND TRANSFER**
The card should be given to the patient immediately after implantation.
The patient should be informed that additional information about the device, including:
- warnings and precautions the patient should be aware of,
- information on the expected service life of the product,
- information on safe use,
- reporting of adverse events,

can be found on the manufacturer's website at the address next to the symbol.

**6. EXPLANATION OF THE SYMBOLS USED**

| | |
|---|---|
| | Patient's name or identification number |
| | Date of implantation |
| | Name and address of the facility/healthcare provider performing the implantation |
| | Information website for patients |
| LOT | Lot number |
| UDI | Unique Device Identifier |
| MD | Medical device |
| | Manufacturer |
| CE | CE marking of conformity |
| | Expiry date |

**Instrucciones de uso** **[ES]**

# LIPOTRIS™

**Gel liposomal compuesto para uso intraarticular, 2 ml**

| | | | |
|---|---|---|---|
| +25°C +2°C | Temperature limit | | Consult instructions for use |
| | Do not re-sterilise | | Caution |
| | Do not reuse | MD | Medical device |
| | Do not use if package is damaged and consult instructions for use | UDI | Unique device identifier |
| STERILE | Sterilized using steam or dry heat | | Distributor |
| | Single sterile barrier system with protective packaging outside | | Non-pyrogenic |
| | Date of manufacture | REF | Reference number |
| CH REP | Swiss Authorized Representative | UK RP | UK Responsible Person |

Not all symbols appear on the labeling.

For more information please refer to the Summary of Safety and Clinical Performance available in the Eudamed database.

**To be used exclusively by a medical doctor.**

Date of issue: 01/2026
No. of the latest revision of the instructions for use: 01/2026

**Manufacturer:**
**Biovico Sp. z o.o.**
Hutnicza 15 B
81-061 Gdynia, Poland, EU
+48 58 660 44 88
office@biovico.com
www.biovico.com

CE 1434

**Global Distributor:**
**Implai Sp. z o.o.**
Hutnicza 15 B
81-061 Gdynia, Poland, EU
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office@implai.com
www.implai.com

## INSTRUCTIONS FOR COMPLETING THE IMPLANT CARD [EN]

**1. PURPOSE OF THE IMPLANT CARD**
The implant card is a document given to the patient after the implantation of a medical device, containing:
- product identification data,
- manufacturer's data,
- data of the implanting person and patient's data.

Its aim is to ensure that the patient and the healthcare system can quickly identify the device and respond effectively to medical incidents.

**Composición**
1 ml contiene:

| | |
|---|---|
| Hialuronato sódico | 22,000 mg |
| 1-palmitoil-2-oleoilfosfatidilcolina (POPC) | 0,800 mg |
| Cloruro sódico | 9,060 mg |
| Hidrogenofosfato de disodio | 0,241 mg |
| Dihidrogenofosfato sódico dihidratado | 0,047 mg |
| Agua para inyección | c.s.p. |

**Descripción**
Lipotris™ es un gel liposomal compuesto para aplicación intraarticular, desarrollado a partir de ácido hialurónico y liposomas. El ácido hialurónico del gel se obtiene en procesos de fermentación bacteriana y los liposomas se forman a partir de 1-palmitoil-2-oleoilfosfatidilcolina (POPC) de origen sintético. Ambos componentes de la formulación son capaces de interactuar creando un material compuesto con propiedades tribológicas únicas. El producto sanitario es estéril y no pirogénico.

**Indicaciones**
Dolor y limitación de la movilidad articular como consecuencia de lesiones postraumáticas o degenerativas (incluida la osteoartrosis).

**Contraindicaciones**
El producto sanitario no debe utilizarse en pacientes:
- con hipersensibilidad conocida a cualquiera de los ingredientes del producto;
- con artritis séptica;
- con dermatosis en el lugar previsto de la inyección;
- que estén tomando anticoagulantes.

**Precauciones**
Durante el procedimiento deben tomarse todas las precauciones necesarias para prevenir la artritis séptica.
Producto sanitario indicado exclusivamente para la inyección intraarticular.
No utilizar productos con sales de amonio cuaternario para desinfectar la piel antes de efectuar la inyección, ya que el hialuronato sódico puede precipitar en su presencia.
Debido a la ausencia de datos clínicos suficientes, el producto sanitario no debe utilizarse en niños ni en mujeres embarazadas o en período de lactancia.
El producto sanitario no se debe utilizar si el autoinyector estéril presenta daños.
El producto sanitario no se debe volver a esterilizar.
No utilizar el producto sanitario después de la fecha de caducidad indicada en el envase.
El producto sanitario está destinado a ser utilizado en un único paciente durante un único procedimiento.
Conservar a una temperatura de +2°C a +25°C. Proteger de la humedad y la luz solar. El producto sanitario debe almacenarse en un lugar inaccesible para los niños.

**Posibles reacciones adversas**
Los estudios de biocompatibilidad han confirmado la alta seguridad del producto sanitario. En el lugar de la inyección pueden aparecer síntomas transitorios como dolor, enrojecimiento e hinchazón. Estos síntomas pueden reducirse enfriando el lugar de la inyección durante 5–10 minutos después del tratamiento.
En caso de dolor, puede ser beneficioso el uso concomitante de analgésicos orales y antiinflamatorios.