

HILLARIA[®]

Dosage Form and Composition

1 sterile syringe in one box

Each syringe contains 5 mL **Hillaria**[®]

1 mL **Hillaria**[®] contains 20 mg cross-linked Hyaluronic acid and 2 mg non cross-linked Hyaluronic acid

Mechanism of Action

The formation of tissue adhesions is a frequent consequence following surgical interventions. The adhesions occur as a result of adjacent internal organs coming into contact and forming fibrous tissue between them. Adhesion formation triggers a series of biological processes, including an acute inflammatory response due to damage to the peritoneal mesothelium. This inflammation encourages the growth of fibrous adhesions, which can cause various post-operative symptoms, such as chronic pelvic pain, bowel obstruction, restricted movement, dyspareunia, infertility, and an elevated risk of complications in subsequent operations. As a result, a second surgical procedure may be necessary to remove fibrous tissues.

To ensure optimal surgical outcomes and prevent the development of post-surgical adhesions, it is recommended to use **Hillaria**[®], which creates a physical barrier between adjacent tissues and remains in place for an adequate duration to avoid adhesion formation while the injured tissues heal. This product fully degrades within six months. Therefore, it can also prevent the occurrence of delayed adhesions.

Description

Hillaria[®] is a viscous gel with high transparency and biodegradability. This sterile gel is produced by crosslinking a specially designed hyaluronic acid, which is a fundamental component of human connective tissue as well as epithelial and mesothelial tissue. **Hillaria**[®] has the capability of adhering to tissue surfaces and the abdominal wall, creating a barrier that effectively prevents the formation of adhesions.

Indications

Hillaria[®] is indicated for laparotomic or laparoscopic abdominal interventions and hysteroscopic interventions for reduction of post-surgical adhesion formation.

Contraindications

- Known hypersensitivity to hyaluronic acid and Gram-positive bacteria.
- As all other implant materials, the device must not be used in patients with active infection and/or contamination of the surgical site.

- Due to a possible risk of impairment with regard to the healing process, the product must not be used in bowel resections and surgeries involving anastomotic sites.

Instructions for Use

- After bringing the product to room temperature, open the pouch and transfer the syringe into the sterile field, adopting the standard aseptic techniques.
- Remove the protective cap on the tip of the syringe and insert the cannula/applicator.
- For laparotomic procedures, 18G needles and for laparoscopic procedures 230 mm cannulas are recommended. Cannulas can be attached via the integrated connector.
- After aspiration of all irrigation fluid, apply the gel inside to completely cover all anatomical sites where adhesion prevention is desired.
- Even if the thickness of the gel applied does not influence the product's efficacy, it is recommended to apply a 1-2 mm thick layer of gel.
- **Do not irrigate** after application of the product.

Special instructions for pelvic-gynecological surgeries

- Lift the ovary away from pelvic sidewall and apply a single layer of gel to cover the ovarian fossa and posterior surface of the ovary.
- Return the ovary to its normal anatomical position and apply a single layer of gel to cover the anterior portion of the ovary.

After placement - all surgeries

- Do not apply irrigation fluid to the sites coated with **Hillaria®**.
- Do not attempt to relocate the gel once applied.

After completely covering the site once, do not apply additional gel to that site. If a single layer of gel does not adequately cover the site, additional layers can be applied next to the previously applied gel. Avoid applying additional layers of gel on top of one another

Storage

- Store the product at a temperature between 2-25°C.
- Do not freeze or expose to extreme heat.
- Freezing of the product can result in severe bubbles formation. Do not use the product in this case as the performance cannot be guaranteed.
- The content is fragile.
- Shelf life is 2 years, correctly preserved.