IALURIL® Prefill
Sterile solution of sodium hyaluronate (1.6 % - 800 mg/50 ml), sodium chondroitin sulphate (2% - 1 g /50 ml) and calcium chloride (0.87% - 440 mg/50 ml)

50 ml Pre-filled syringe with Luer-Lock Adapter and IALUADAPTER®
For intravesical instillation

PRODUCT DESCRIPTION:

The urothelium is covered by a layer of polyanionic molecules mainly made up of glycosaminoglycans (GAGs). This is a class of aminosugars which form an impermeable, protective and neutralizing barrier against the toxic and irritating substances present in urine (e.g. bacteria, microcrystals, proteins, ionic and non-ionic residue etc.), preventing them from being reabsorbed at a systemic level.
Of the GAGs that form this barrier, chondroitin sulphate and hyaluronic acid play a central role in its functioning.
Qualitative and quantitative variations at various levels of the two GAGs deactivate the barrier effect, causing a series of conditions which can foster the onset of cystitis of various kinds (e.g. interstitial cystitis, recurring cystitis caused by infections, cystitis induced by antitumoral agents, cystitis induced by radiation, traumatic cystitis).
IALURIL Prefill®, a balanced association of sodium hyaluronate, chondroitin sulphate and calcium chloride, can be functionally integrated into the barrier thanks to the action of the calcium chloride, re-establishing its protective function.

INDICATIONS:

IALURIL® Prefill is indicated to re-establish the glycosaminoglycan layers (GAGs) of the urothelial vesical tissue in cases in which their loss can cause frequent and recurring problems (such as, for example, cystitis of varying etiology).
IALURIL® Prefill is also indicated in cases where the loss of the glycosaminoglycan layers (GAGs) is associated with forms of chronic inflammation, in which their composition and integrity appears compromised in different ways.

COMPOSITION:

Each 50 ml pre-filled syringe of IALURIL® Prefill contains: water, calcium chloride, hyaluronic acid sodium salt, sodium chondroitin sulphate.

FREQUENCY OF USE:

The contents of one syringe should be instilled according to the following plan:
1 instillation a week in the first month
1 instillation every two weeks in the second month
In the following months, 1 instillation a month until the stable remission of the symptoms is recommended, or according to medical advice.

INSTRUCTIONS FOR USE:
IALURIL® Prefill can be administered with a catheter or IALUADAPTER®.
The choice of the method of administration for each patient is carried out according to medical advice.

INSTRUCTIONS FOR USE OF IALURIL® PREFILL WITH A CATHETER:

1. After the patient has urinated spontaneously, empty the bladder of all traces of urine by inserting a suitable sterile catheter through the external urethral meatus and wait for all the urine in the bladder to be evacuated (use of an 8 Ch catheter is recommended during this stage);
2. Screw the plunger rod supplied with the pre-filled syringe, until it is perfectly in place;
3. Mount the Luer-Lock Adapter on the top of the pre-filled syringe and apply onto it the sterile catheter previously placed in the bladder;
4. Slowly instil into the bladder all the solution contained in the syringe through the catheter;
5. When the product has been instilled into the bladder, carefully remove the catheter with the syringe and throw it away;
6. Keep IALURIL® Prefill in the bladder for as long as possible (minimum time recommended: 30 minutes).

INSTRUCTIONS FOR USE OF IALURIL® PREFILL WITH IALUADAPTER®:

1. Before starting the treatment, the patient is asked to urinate and to make sure to completely empty the bladder before the instillation .
2. Screw the plunger rod supplied with the pre-filled syringe, until it is perfectly in place;
3. Fasten the IALUADAPTER® on the top of the pre-filled syringe with a half twisting motion to achieve a stable attachment.
4. Slowly instil into the bladder all the solution contained in the syringe through the IALUADAPTER®;
5. When the product has been instilled into the bladder, carefully remove the IALUADAPTER® with the syringe and throw it away;
6. Keep IALURIL® Prefill in the bladder for as long as possible (minimum time recommended: 30 minutes).

PRECAUTIONS FOR USE:
Administration of IALURIL® Prefill by catheter or by IALUADAPTER® may only be carried out by medical practitioners or may be self-administered after appropriate training. All the operations must be carried out in an appropriate environment and with care as, for example in the case of interstitial cystitis, the patient:

- is particularly exposed to the onset of bacterial cystitis which may exacerbate the symptoms of the existing pathology
- complains of pelvic pain
- deliberately urinates less frequently in order not to aggravate the pelvic pain triggered off by the act of urination (muscular hypertone induced by pain).

Wash hands thoroughly, preferably using an antibacterial/detergent and then wear sterile gloves before proceeding with the preparation and administration of IALURIL® Prefill.
Carefully follow the operations suggested by the normal protocol for intravesical instillations management.

WARNING:
Do not use IALURIL® Prefill after the "use by" date shown on the packaging.
Do not use the Luer-Lock Adapter if the packaging is open or damaged.
Do not use the IALUADAPTER® if the packaging is open or damaged.
Do not use IALURIL® Prefill if the packaging is open or damaged.
Do not use IALURIL® Prefill if there are visible impurities or precipitates in the product.
Do not sterilize again. IALURIL® Prefill is for use once only.
Do not reuse portions of unused solution.
Do not reuse to avoid any risk of contamination.
After opening, the device must be used immediately and disposed of after use.
Store at between 0° and 25°C and far from sources of heat.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

INTERACTIONS:
No interactions between IALURIL® Prefill and medicinal products normally used by patients with cystitis of varying etiology are known at the present time.

CONTRAINDICATIONS:
No contraindications deriving from the use of the device are known.
Do not use IALURIL® Prefill in the case of known hypersensitivity to any of the components.

SIDE EFFECTS:
IALURIL® Prefill is usually well tolerated and causes few, if any, adverse reactions. Occasionally, patients could experience local reactions (irritation, burning) as a result of the instillation procedure itself, rather than from IALURIL® Prefill.
Suspend the treatment in the event of the onset of any undesired effect.

Each PRE-FILLED SYRINGE is for one patient only
IALURIL® Prefill - 50 ml pre-filled syringe is steam sterilized.
IALURIL® Prefill - 50 ml pre-filled syringe is Latex Free.

Luer-Lock Adapter is sterilized using ethylene oxide. CE 0482
Manufacturer: Primed Halberstadt Medizintechnik GmbH, StraBe des 20. Juli 1
D-38820 Halberstadt, Germany

IALUADAPTER® is sterilized using Gamma ray. CE 1011
Manufacturer: DISPOMEDICOR Kft.
4032 Debrecen, Füredi ùt 98.
Hungary

The medical device must be administered to patients by medical practitioners or can be self-administered after appropriate training and under doctor control.

LAST PATIENT INFORMATION LEAFLET REVIEW: March 2019
IALURIL® Prefill - 50 ml pre-filled syringe

Year of CE certification: 2013

MANUFACTURER:
IBSA FARMACEUTICI ITALIA SRL
Via Martiri di Cefalonia, 2
26900 Lodi (LO) - ITALY
info@ibsa.it

DISTRIBUTOR:
Name and address of Distributor

Sterilized using ethylene oxide

Sterilized using gamma ray

See the instructions for use

Caution: read the warnings carefully

Use by…

Disposable

Storage temperature

Steam sterilised

Lot