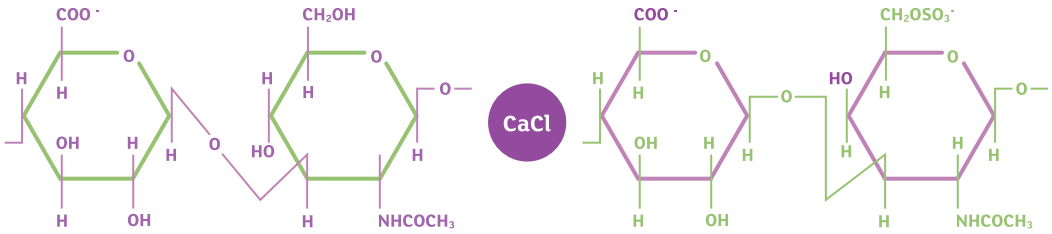
# iAluRil®: Product Information

## Product Name

iAluRil® Prefill

Sterile solution of sodium hyaluronate (1.6% - 800 mg/50 mL) and sodium chondroitin sulphate (2% - 1 g /50 mL)

50 mL pre-filled syringe
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 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 cystitises of various kinds (e.g. interstitial cystitis, recurring cystitises caused by infections, cystitises induced by antitumoral agents, cystitises induced by radiation, traumatic cystitises).

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, interstitial cystitis, bladder pain syndrome, treatment and prevention of recurrent urinary tract infection, cystitis as a result of Bacillus Calmette – Guerin therapy, or chemical and radiation therapy.

iAluRil® Prefill is also indicated in the 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 the first month

1 instillation every two weeks the second month

In the following months, 1 instillation a month until the stable remission of the symptoms is recommended.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### Instructions For Use

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 the full leakage of urine collected in the bladder (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 on it the sterile catheter previously placed in the bladder;
4. Instil into the bladder all the solution contained in the syringe through the catheter;
5. 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 may only be carried out by qualified personnel. All the operations must be carried out under controlled sterility and delicately as, for example in the case of interstitial cystitis, the patient

- is particularly exposed to the onset of bacterial cystitises which exacerbate the symptoms of the pathology in course
- 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 possibly 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 vesical catheter management.

### Warning

Do not use iAluRil® Prefill after the "use by" date shown on the packaging.

Do not use iAluRil® Prefill if the packaging is open or damaged.

Do not use the Luer-Lock Adapter 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 REACH AND SIGHT OF CHILDREN

### Interactions

No interactions between iAluRil® Prefill and medicinal products normally used by patients with cystitises of varying etiology are known at the present time. There is currently not enough clinical data to determine if iAluRil® interferes with BCG efficacy.

### 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. iAluRil® has not been tested in pregnant women, lactating women, and children.

### Side Effects

Clinical trial data indicate a low risk profile for iAluRil® Prefill: urinary tract infections (likely associated with repeat catheterisation) and urinary storage symptoms were the only adverse events reported in the clinical development.

According to post-marketing experience, the urinary storage symptoms (increased frequency and urgency) has been recorded with very rare frequency.

Contact your health professional in case of any unexpected adverse 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.

### To Be Sold on Medical Prescription Only

It may only be administered by a doctor or by qualified personnel under the direct responsibility of a doctor.

**Date of preparation: July 2014**

**Year of CE certification: 2013**

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