

INSTYLAN

Sterile Solution based on hyaluronic acid for intravesical irrigation

Qualitative composition

Sodium hyaluronate.

Excipients: Water for injection, Sodium Chloride, Phosphate buffer

Classification of the product

Medical device –sterilized and pyrogen-free- Class IIa.

Package

50 ml pre-filled disposable plastic bag which contains 0.16 % (80mg/50ml) of hyaluronic acid solution.



Each Package contains:

- 1 plastic bag with INSTYLAN Sterile solution. The medical device has been sterilized by steam sterilization

Indications

INSTYLAN is intended for irrigation into bladder cavity that provides the formation of a viscous elastic film on the surface of mucous layer for:

- protecting it from external effects during various surgeries (ureteroscopy, cystoscopy, transurethral resection of adenoma and radiation therapy of lesser pelvis organs etc)

- protecting it from harmful impact of bladder content (urina) in case of injury or inflammation of mucous layer of bladder, like cystitis.

INSTYLAN is intended for irrigation of the bladder during using urological catheter. The irrigation provides temporary protection and restoration of bladder mucous layer during various surgeries (urethra cystoscopy, radiation therapy etc).

Warnings and special precautions for use

- Do not use if the solution is not transparent and colorless.
- Do not use if the package is opened or damaged.
- The product must be used immediately after opening.
- The product is intended for single use. After use, the unused product is no longer sterile. Do not use product residuals;
- Do not reuse. Once the product has been used for the first time, any residuals of the product are not suitable for the repeated use as the product is no longer sterile.
- Do not resterilize. Repeated sterilization may cause cross-contamination.
- Do not freeze.
- The product must not be administered orally.

Special warning

- Do not use the Solution in patients with known hypersensitivity to hyaluronic acid, with a history of allergic reactions to any component of the product.
- The irrigation into bladder should be provided by a trained medical specialist in specialized premise with appropriate equipment and aseptic conditions.
- Do not inject the solution into blood vessels.
- Do not use the product with children, pregnant and lactating woman.

Adverse reactions and side effects

None.

How to use

- Check package integrity before use.
- Check the expiration date indicated on the bag. Do not use after the expiry date.
- Take one of the plastic bag with INSTYLAN Solution.
- Make sure that the bladder of the patient has been previously emptied
- Remove the cap
- Irrigate the patient bladder using urological catheter.

For cystitis treatments:

- It is suggested to use the sterile solution INSTYLAN weekly for the first month and with less frequency in the following months.



The frequency of use of sterile solution INSTYLAN must be determined by the doctor who established the treatment.

Shelf life

2 years in an intact package.

How to store

Store at the temperatures from 5 °to 30° C (included), away from direct light and heat, in the adequately closed packaging.
The expiry date is applied to the product which is correctly stored in an intact package.

Disposal

The product must be disposed in accordance with applicable laws on medical waste.



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Symbols used on the packaging			
	Do not reuse – for single use		Manufacturer
	Batch code		Sterilized using steam or dry heat
	Expiry date		Do not re-sterilize
	Do not use if the package is opened or damaged		Protect from light and heat
	Consult instructions for use		Temperature limit for warehouse storage
	Non - pyrogenic		Date of Manufacture