

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 containing 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 to:

- protecting it from external effects during various surgeries (ureteroscopy, cystoscopy, transurethral resection of adenoma and radiation therapy of lesser pelvis organs, etc)
- protect it from the harmful impact of bladder content (urina) in case of injury or from inflammation of the mucous layer of the bladder, like cystitis.

INSTYLAN is intended for irrigation of the bladder when using a 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 packaging has been opened or is 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, or those with a history of allergic reactions to any component of the product.
- Irrigation into the 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 pregnant or lactating woman, or children.

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 bags containing INSTYLAN Solution.
- Make sure that the bladder of the patient has been previously emptied
- Remove the cap
- Irrigate the patient's bladder using an urological catheter.

For cystitis treatments:

- It is suggest that the sterile solution INSTYLAN is used 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 temperatures between 5° to 30° C (inclusive), away from direct light and heat, in the adequately sealed packaging. The expiry date is applied to the products which are correctly stored in an intact package.

DISPOSAL

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

 <p>Diacio Biofarmaceutici S.R.L. Via Flavia 124, 34147 Trieste-Italy</p> <p> Medical device according to Directive 93/42/ CEE 1936</p>	Symbols used on the packaging and box labels			
		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 has been opened or is damaged		Protect from light and heat
		Consult instructions for use		Temperature limit for warehouse storage
		Non - pyrogenic		Date of Manufacture