

### Description

HYACYST is a medical product that consists of a solution from highly purified Sodium salt of hyaluronic acid of non-animal origin. It is utilised as a sterile rinsing fluid for urothelial changes in the ureter, urinary bladder and the initial portion of the urethra.

HYACYST has no pharmacological effect on the tissues after introduction. Its effect is based on physical properties.

For instance, it is known that urothelial inflammations lead to a loss of hyaluronic acid in the mucous membrane.

A loss of hyaluronic acid in the vascular mucous membrane especially occurs with interstitial cystitis (IC). The urothelium can be regenerated through the substitution of hyaluronic acid.

The following occurs:

- Regulation of the permeability of the bladder wall.
- Containment of the inflammatory response.
- Support of wound healing.

### Use as directed

HYACYST is a sterile hyaluronic acid solution which is instilled into the urinary bladder with the help of a catheter. This solution/lavage fluid serves for the regeneration of destroyed/changed urothelium (interstitial cystitis (IC)) in the urinary bladder and the deferent urinary passages.

- If you have further questions, please ask your doctor or healthcare Professional.
- This device has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor immediately.

### Intended Use

- Interstitial cystitis
- Painful bladder syndrome
- Glycosaminoglycan (GAG) layer deficiency
- Hemorrhagic cystitis
- Recurrent bacterial cystitis
- Radiation cystitis
- Chemotherapy induced Cystitis

### Composition

HYC-4050 (50ml HYACYST in 50-ml vial contains 40 mg of sodium hyaluronate).

HYC-1250 (50ml HYACYST in 50-ml vial contains 120 mg of sodium hyaluronate).

### Reference for Use

The total volume of the solution is instilled by means of a syringe and instillation catheter in the urinary bladder after complete drainage of the urinary bladder.

First withdraw the solution into a syringe and connect the syringe to an appropriate catheter using the Luer Lock connector. In order to achieve optimal results, HYACYST should remain as long as possible in the urinary bladder (min. 30 minutes. max. 2 hours). In order to alleviate interstitial cystitis, it is recommended in the available clinical literature to carry out the treatment once a week over four weeks.

HYACYST should be used once thereafter a month as a maintenance therapy until the symptoms have disappeared. If no success is recognizable after 4 weeks, the possibility of a different therapy should be considered.

### Overdose

It is important to use Hyacyst as instructed. If you accidentally use a higher dose or used it before the scheduled time, other than instructed, inform your doctor or healthcare professional.

### If you forget to use HYACYST

If you forget to use HYACYST, use it as soon as possible. However, if it is almost time for your next dose, skip the missed one and go back to your regular dosing schedule.

### If you stop using HYACYST

If you want to stop using HYACYST talk to your doctor or other healthcare professional first. If you have any further questions on the use of this product, ask your doctor or healthcare professional.

### SIDE EFFECTS

Hyacyst is well tolerated and causes few, if any side effects. Occasionally, the insertion of the catheter into the bladder may cause irritation.

### WARNING

Do not use HYACYST in patients with a known sensitivity to hyaluronic acid. Do not use damaged vials. Only intended for one-time use. Do not use in pregnant women and adolescents under age 18, since there are no experience available concerning this. As with any urological application, a urinary tract infection can arise during the placement of the catheter.

### Storage












Store at room temperature (2-30 °C). Do not freeze.

### Form of Supply

HYC-4050 50ml Vial contains 50 ml of HYACYST solution (40mg sodium hyaluronate).

HYC-1250 50ml Vial contains 50 ml of HYACYST solution (120mg sodium hyaluronate).

### Symbols

	Sterilization with steam
	Not for re-use
	Pay attention to instructions for use
	Storage temperature
	Expiry Date
	Batch designation
	Date of manufacture
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	CE number commensurate with MDD 93/42/EEC 2292 is the number of the "denominated location"

### Sales and Distribution:

Syner-Med (Pharmaceutical Products) Ltd  
Syner-Med House  
120 High Street  
Purley, Surrey  
UK  
CR8 2AD  
+44(0)208 655 6380  
mail@syner-med.com

### Manufacturer:

Istem Medikal  
İvedik Org. San. Böl.  
661. Sok. No:4 Ostim-Ankara/  
TURKEY

### Manufactured in Germany:

BioScience GmbH  
Rheinstraße 96, D-56235  
Ransbach-Baumbach/  
GERMANY