

Sterile Sodium Hyaluronate Solution INSTRUCTIONS FOR USE

[EN]

Description

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

HYACYST has no pharmacological effect on the tissue after application. 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 instillation catheter. This solution/lavage fluid serves the regeneration of destroyed/altered 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 on this leaflet, please inform 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

- 50 ml HYACYST in 50ml syringe contains 120 mg of sodium hyaluronate.
- 50ml HYACYST in 50ml syringe contains 40 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.

You can directly use the pre-filled syringe content by removing the cap from the syringe and connecting the syringe to an appropriate catheter using the Luer Lock connector.

If the catheter without a Luer-Lock connection is used instead of the instillation catheter, the supplied catheter syringe adaptor should be used. The Luer-Lock end of the catheter syringe adaptor should be connected to the pre-filled syringe and the catheter adaptor end should be connected to the catheter previously inserted into the bladder.

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 larger dose or used it before your 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. Occasionally, the insertion of the catheter into the bladder may cause irritation.

Warnings

Do not use HYACYST in patients with a known sensitivity to hyaluronic acid. Do not use damaged syringe. Only intended for one-time use. Do not use in pregnant women since there are no experience available concerning this. HYC-4050 is not recommended to be used in adolescents under the age of 6 and HYC-1250 is not recommended to be used in adolescents under the age of 18 since there are no clinical trials available concerning this. As with any urological application, a urinary tract infection can arise during the placement of the catheter.

Storage

Store at 2-30° C. Do not freeze.

Form of Supply

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















HYC-1250 A contains a syringe of 50 ml of HYACYST solution (120 mg sodium hyaluronate) and catheter syringe adaptor.

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

HYC-4050 A contains a syringe of 50 ml of HYACYST solution (40 mg sodium hyaluronate) and catheter syringe adaptor.

The box includes an optional hydrophilic instillation urinary catheter or catheter syringe adaptor.

Symbols

	Sterilized using aseptic processing techniques		Do not re-use
	Storage temperature		Do not re-sterilize
	Pay attention to instructions for use		Expire date
	Batch number		Date of manufacture
	Keep away from sunlight		Keep dry
	Do not use if package is damaged		Latex free
	CE number commensurate with MDD 93/42/EEC 2292 is the number of the notified body		
	Manufactured by: İSTEM MEDİKAL Malıköy Anadolu O.S.B. Mah. 29 Ekim Cad. No:41 Sincan/Ankara/TURKEY Tel: 0312 394 55 62-63 / www.istemmedikal.com		