

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 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

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

HYC-4050 S (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. 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, 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 syringe. Only intended for one-time use. Do not use in pregnant women since there are no experience available concerning this. HYC-4050S is not recommended to be used in adolescents under the age of 6 and HYC-1250S 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 room temperature (2-30 °C). Do not freeze.

Form of Supply

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

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

Symbols



Sterilized using aseptic processing techniques



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"

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