

Sodium Hyaluronate

GAG Replenisher for Urology Pre-filled Syringe with Luer-lock Adapter

Indication

For temporary replacement of the glycosaminoglycan (GAG) layer of the bladder.

Description

The glycosaminoglycan (GAG) layer on the luminal surface of the bladder wall is believed to provide a protective barrier against microorganisms, carcinogens, crystals and other agents present in the urine and has been identified as the primary defence mechanism in protecting the transitional epithelium from urinary irritants. Deficiencies in this GAG layer of the bladder epithelium may destroy its barrier function and allow the adherence of bacteria, microcrystals, proteins and ions, or the movement of ionic and nonionic solute residues (i.e. urea) across the epithelium. Solatum™ Sodium hyaluronate GAG replenisher has been developed to temporarily replenish the deficient GAG layer on the bladder epithelium. The active substance is a highly purified sodium salt of hyaluronic acid (HA) or hyaluronate.

Contents

Each Solatum™ prefilled syringe contains 40mg sodium hyaluronate in 20ml solution.

Solatum™ is supplied with a separately packed sterile Luer-lock adaptor in the carton.

Directions

The patient should empty their bladder and have a urethral catheter inserted. Any residual urine should be drained. Connect the supplied luer-lock adapter (or other female luer-lock adapter) between the pre-filled syringe and pre-inserted urethral catheter (not supplied). Instill the entire volume of the Solatum™ solution into the bladder. Discard any unused portion.

For best results, Solatum™ should be retained in the bladder for as long as possible (a minimum of 30 minutes), ideally up to 60 minutes.

Dosage Regimen Recommended

There is evidence that the GAG layer of the bladder is deficient in patients with chronic cystitis (interstitial cystitis, painful bladder, recurrent bacterial cystitis, radiation cystitis, cystitis associated with trauma).

To alleviate cystitis associated with these conditions, it is recommended that Solatum™ be instilled into the bladder each week for 4 – 6 treatments and then monthly until symptoms resolve – usually 6 months in total. The patient should stop treatment and the patient and their Physician and/or Specialist Nurse should establish if symptoms have resolved. Treatment can be continued for longer on the decision of the Physician and/or Specialist Nurse.

Precaution

Do not administer to patients with known hypersensitivity reactions. Discontinue use if adverse reactions are experienced. As no clinical evidence is available on the use of hyaluronic acid in children, pregnant and lactating women, treatment with Solatum™ is not recommended in these patients.

Warning

For single use only.

Discard after use.

KEEP OUT OF THE REACH OF CHILDREN.

Storage

Store at room temperature (2 – 25°C).

Do not freeze.

Supplied

1 x 20ml Prefilled Syringe of Solatum™ 40mg.

1 x Primed Luer-Lock Adapter (CE 0482).

Adverse Event

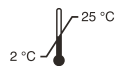
Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should be reported to Solatumfarma on 01922 895 262.

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Solatumfarma Ltd.,
Pure Offices, Plato Close, Warwick,
CV34 6WE, United Kingdom.
Telephone: +44 (0)1922 895 262
www.Solatumfarma.com

