

HYACYST[®]



(Sodium Hyaluronate) 40mg/50ml
120mg/50ml Pre-Filled Syringes and Vials

A patient's guide to treatment with Hyacyst[®]



This guide is intended to provide you with information on what Hyacyst[®] is and what to expect from your treatment.

Hyacyst[®] is a bladder instillation treatment for Interstitial Cystitis / Painful Bladder Syndrome (IC/PBS).

Provided as a service to medicine by



What is Interstitial Cystitis / Painful Bladder Syndrome (IC/PBS)?

Interstitial Cystitis (IC) is a chronic inflammation of the bladder wall, which can also be diagnosed as Painful Bladder Syndrome (PBS). The causes of IC and PBS are believed to result from a number of factors. IC and PBS symptoms may resemble a bacterial bladder infection, however short term antibiotics are not effective. Symptoms of IC include; urgency, frequency and nocturnal micturition, with associated bladder and suprapubic pain with negative urine cultures. The course of the disease is marked by flare-ups and remissions¹.

Indications suggest that the IC and PBS are due to deficiencies in the components of the Glycosaminoglycan (GAG) layer of the bladder².

What causes IC/PBS?

The factors most likely to play a significant role include^{3,4};

- Disease
- Allergies
- Inflammation
- Infection
- Mast cell activation
- Bladder permeability, secondary to injury
- Subsequent potassium damage

No single theory has been proven to explain the symptoms in all cases, thus, many believe it to be multifactorial in nature⁵.

The Glycosaminoglycan (GAG) layer of the bladder has been proposed to play a crucial role in protecting the bladder from harmful substances in urine⁶. When the GAG layer is damaged, the protective impermeability function is lost. Potassium, proteases and other potentially harmful urinary solutes are allowed to penetrate into the bladder, where they may stimulate sensory neurones. This will result in inflammation and the characteristic symptoms of IC/PBS such as pain and urinary urgency⁷.

How common is IC/PBS?

Interstitial Cystitis predominantly affects women (90%), occasionally men and rarely children. It is indiscriminate of culture, socioeconomic background and age. The onset is usually between the ages of 30-70 years with a median age of 43⁸. The prevalence of the disease seems to be increasing among young and middle aged women⁹.

Symptoms

The symptoms of IC/PBS may initially be misdiagnosed as a “common” bladder infection or urinary tract infection. Commonly patients experience:

- Pain and discomfort
- Frequently needing to pass urine
- Sensation of needing to pass urine urgently
- Frequently getting up during the night to pass urine

What is Hyacyst® and what is it used for?

Hyacyst® is a clear solution of sodium hyaluronate. Sodium Hyaluronate temporarily replaces and replenishes deficient components of the glycosaminoglycan (GAG) layer in urinary bladder. This helps to relieve the symptoms of pain, frequency and urgency of urination¹⁰.

How is Hyacyst® administered?

Hyacyst® is instilled directly into the bladder with a tube called a catheter. This procedure will be carried out by your Urology Doctor or Nurse. Hyacyst® should remain in the bladder for as long as possible (minimum 30 minutes).

How long do I need Hyacyst® for?

Your doctor or nurse will advise you of the duration of treatment with Hyacyst as it varies from patient to patient. Generally a patient would receive treatment with Hyacyst® weekly for 4 weeks, followed by monthly until symptoms resolve.

Possible side effects

Hyacyst is well tolerated and cause few, if any, adverse reactions. Occasionally, the insertion of a catheter can cause urethral irritation. If this becomes difficult to administer consult your doctor or other healthcare professional.

Useful tips: preparing for your bladder instillation of Hyacyst®

- Visit the toilet a few minutes before your appointment. This helps to ensure that the bladder is as empty as possible before Hyacyst® instillation
- Minimise the amount of fluid you drink 6 hours before Hyacyst® is due to be given. You may take sips of water or small amount of fluid with medications
- If you take diuretics (water tablets) consult your doctor or nurse
- Eat normally before the treatment
- If you suspect you have a urine infection or are pregnant, contact the clinic for advice immediately

What else can help you to cope with IC/PBS?

Even though IC/PBS is a difficult condition to cope with, there are lots of ways to help reduce the symptoms and make life a little easier. Not all of these will work for you.

Diet

Most (but not all) people with IC/PBS find that certain foods make their symptoms worse. There are four foods that patients most often find irritating to their bladders: citrus fruits, tomatoes, chocolate and tea/coffee.

Other foods are alcohol, carbonated drinks and spicy foods. The list of foods that have been reported to affect IC/PBS is quite long, but not all foods affect all patients the same way. For this reason, each patient must find out how foods affect his or her own bladder.

Lifestyle and self-help

Patients find that stress can trigger their symptoms. Relaxation techniques, meditation or massage, as well as gentle exercise, such as walking may be beneficial.

Patients may be inclined to cut down their fluid intake, as they fear having to go to the toilet at an awkward moment. However, this can make the urine very concentrated and can cause more pain. It is important to maintain a balanced fluid intake and drink normally.

Support

Patients suffering from IC/PBS may report anxiety, depression and feelings of isolation. It is good to know that you are not alone and that many people suffer from the disease and have successfully managed the condition. Support is available for patients to share thoughts and feelings with people in similar circumstances.

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For more information on support groups contact:

Cystitis and Overactive
Bladder Foundation (COB)

Tel: 0121 702 0820

Web: www.cobfoundation.org



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HYACYST[®] Abbreviated Prescribing Information

Refer to Package Information Leaflet

Active Ingredient (quantities, qualitative): Each vial/pre-filled syringe contains a sterile solution of highly purified Sodium Hyaluronate (40mg/50mls or 120mg/50mls) of non-animal origin. **Presentation:** Clear Solution for bladder instillation. **Indication:** Replenishment of deficient glycosaminoglycan (GAG) in the bladder. The GAG layer lines the epithelium in the bladder. It acts as a protective barrier, shielding the bladder wall from microorganisms, toxins and urine components that may adversely affect the bladder.

Deficiency or injury to this layer results in increased permeability of the bladder wall and is a leading explanation for the aetiology of Interstitial Cystitis and Painful Bladder Syndrome. **Dosage and administration:** weekly instillation of Hyacyst 40mg/120mg for 4-6 weeks followed by monthly instillation until symptoms resolve. **Contraindications:** Hypersensitivity to Sodium Hyaluronate. **Legal category:** Class IIa Medical Device, CE 2292. **Sales and distribution:** Syner-Med (PP) Ltd. Syner-Med House, 120 High St, Purley, Surrey, CR8 2AD.

Medical Device Class IIa CE 2292

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