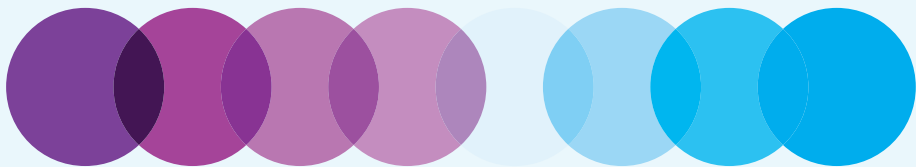


Patient Treatment Diary

iAluRil[®]
with iAluadapter[®]
Combination GAG Therapy



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Recurrent Urinary Tract Infections/ Recurrent Bacterial Cystitis

What is Recurrent Bacterial Cystitis?

Bacterial Cystitis (BC), also known as Urinary Tract Infection (UTI), is an inflammation of the bladder caused by bacteria entering the bladder via the urethra (the tube through which urine is passed from the bladder).

Bacterial Cystitis/UTI occurs most commonly in women. It is estimated that between one or two out of every five women in the UK will get cystitis at some point in their life. Men and children can be affected, although this is less common.

What causes RBC?

Infection is most often caused by a person's own bowel bacteria that are found on the skin surrounding the anus. These bacteria can be spread to the urinary tract by both sexual intercourse and poor personal hygiene; whilst normally harmless, they can cause isolated and/or recurrent UTIs if they enter the urinary tract. Recurrent infections in women with normally functioning urinary tracts are common and rarely result in serious damage to the kidneys. The female urethra (the tube that comes from the bladder to the outside, through which one urinates) is much shorter than that of a male and is closer to the anus. This may go some way to explaining why this condition is more common in women than men. Multiple sexual partners, diabetes and bladder or kidney problems can also increase the risk of developing an infection in some women.

Recurrent Urinary Tract Infections/ Recurrent Bacterial Cystitis

Symptoms of Bacterial Cystitis/UTI

Main symptoms include:

- Burning or stinging pain when urinating (dysuria)
- Frequent need to pass small amounts of urine
- Feeling of urgency to pass urine even when the bladder is empty
- Cloudy/dark urine, which may have a strong smell

Additional symptoms may include:

- Blood in urine (haematuria)
- Mild fever and chills
- Painful sexual intercourse
- Dull pain in the lower back or abdomen
- Fatigue
- Generally feeling unwell
- Nausea

How is it treated?

Treatment of RBC may involve the use of low dose preventive antibiotics or a course of antibiotics at the time of flare-up. If these are prescribed, it is important to finish the course as directed. Your doctor will discuss and prescribe the most appropriate treatment course for you. Some patients may benefit from having a product instilled into their bladder in an attempt to re-build the protective lining, which may reduce the recurrence of re-infection.

Can it be prevented?

Recurrent episodes of cystitis are fairly common and a doctor should always be consulted if cystitis episodes are frequent. If you suffer from RBC, one or more of the following practices may help in preventing another infection:

- Drink at least 2 litres of water each day to flush the bladder and urinary tract
- Maintain good daily personal hygiene
- Urinate before bed and following intercourse
- To avoid spreading bacteria from the anus to the urethra, always wipe from front toward the rear having passed faeces
- Avoid bubble bath and chemicals in bath water, both of which have been implicated in the transference of bacteria to the urethra

Interstitial Cystitis/ Painful Bladder Syndrome

What is Interstitial Cystitis/Painful Bladder Syndrome?

Interstitial Cystitis (IC) is one of a number of chronic pelvic pain disorders that fall under the term Painful Bladder Syndrome (PBS). It is characterised by recurring discomfort or chronic pain in the bladder and surrounding pelvic region and usually results in a significant negative impact on your quality of life because of the frequent need to urinate.

What are the causes?

Often misdiagnosed, the cause of IC remains unknown. Unlike more common forms of cystitis, IC is not caused by bacterial infection and therefore does not respond to antibiotic treatment.

What are the symptoms?

The three classic symptoms associated with IC are:

- **Pain;** pain associated with IC can be felt in the lower abdomen, pelvis, vagina and urethral tube (the tube which connects the bladder to the outside of the body), and is often associated with sexual intercourse. Male IC patients may also experience pain in their testicles and painful ejaculation;
- **Urgency;** the sense of needing to urinate immediately can also be accompanied by discomfort due to sensations of pressure and pain;
- **Frequency;** in severe cases, day and/or night-time frequency of urinating can be up to 50 times per day. An increase in frequency can be the only presenting symptom in the early stages of the condition.

While all three are common and present in the vast majority of cases, it is not impossible to only present with two out of the three.

Interstitial Cystitis/ Painful Bladder Syndrome

What can be done about IC/PBS?

As the exact cause of IC is unknown, there is no cure. However, some treatment options are available that can reduce the severity of the symptoms you may be experiencing and lower the impact that IC has on your quality of life. These options range from taking oral medications to reduce the individual symptoms, to having a product instilled into your bladder in an attempt to re-build the waterproof protective lining of your bladder. By discussing your condition with your doctor or nurse, you will be able to evaluate each option and determine which treatment will work best for you.

Am I alone?

No. You are certainly not alone in suffering from IC:

- There is an estimated 400,000 people in the UK who suffer with IC/PBS, of whom 90% are female and 10% are male;¹
- The average age at disease onset is 30-70 years of age.²

Treatment with iAluRil GAG Therapy

What is iAluRil?

iAluRil is a medical device for the treatment of cases where damage to the GAG layer of the bladder is associated with chronic inflammation and infection. iAluRil can be used to treat:

- Interstitial Cystitis/ Painful Bladder syndrome;
- Chemical cystitis – damage to the bladder lining caused by chemotherapy;
- Radiotherapy-induced cystitis – damage to the bladder lining caused by radiation to the pelvis;
- Recurrent urinary tract infections.

iAluRil works by re-establishing the GAG layer of the bladder to form a protective barrier between the bladder lining, and the irritant compounds found in urine.

How does iAluRil work?

In a healthy bladder there is a natural barrier that protects the bladder lining from the urine. This barrier is called the glycosaminoglycan (GAG) layer. If this barrier is damaged, urine comes into direct contact with the tissues of the bladder lining and over time can cause damage to these tissues. This damage can lead to a range of problems that cause symptoms, such as pain, urgency (the need to go to the toilet immediately) and frequency (the need to go to the toilet more often).

iAluRil contains two of the natural GAGs that form this barrier; hyaluronic acid (HA) and chondroitin sulfate (CS). By administering iAluRil directly into the bladder, these GAGs help to repair the damage to the mucosal layer and restore the bladder's protective coating, relieving these symptoms.

Treatment with iAluRil GAG Therapy

How is iAluRil administered?

iAluRil® is administered directly into the bladder, either using a thin tube (catheter) passed through the urethra (the passage through which your urine comes out when you go to the toilet) or by using the iAluadapter® fitted to the end of the syringe.

Before administering iAluRil® you will need to urinate and then, if you have a catheter in place, the bladder can be further emptied.

When the liquid from the syringe has been passed into your bladder it should be held there for at least 30 minutes. The bladder can then be emptied by urinating as normal.

This is a relatively painless and routine procedure, which may initially be carried out by a doctor or a nurse, however, many patients can be taught to do this themselves as it is very simple. If this is something that you feel you would prefer to do, then do discuss this with your doctor or nurse and they will be able to offer more advice.

How long will my treatment last?

iAluRil treatment begins with a course of instillations given once a week for the first month.

Further instillations can then be given at varying intervals dependent on the condition being treated¹:

Painful Bladder Syndrome/ Interstitial Cystitis: at weeks 6 and 8*

Prevention of Urinary Tract Infections: monthly for 5 months

Treatment with iAluRil GAG Therapy

Chemical induced cystitis (Including BCG): weekly for another 4 weeks

Radiation induced cystitis: at weeks 6, 8 and 12.

Once the symptoms have improved, the treatment course can be finished. If the symptoms reoccur, the initial course of instillations can be repeated in order to settle the symptoms down again or according to medical advice.

Will I get any side effects?

iAluRil is usually well tolerated and causes few, if any, adverse reactions. Occasionally the administration process can cause minor irritation; however, this is caused by the procedure and not the product itself.

If you do experience any side effects discuss them with your nurse or doctor and between you a decision can be made whether to continue with or stop treatment.

*One instillation of iAluRil should be given weekly for the first month, followed by one instillation every two weeks for the second month. In the following months, one instillation a month should be given until symptoms resolve to the satisfaction of both the clinician and patient.

Treatment with iAluRil GAG therapy

Maintaining a healthy diet - Are there any foods to avoid?

What about diet?

Diet is an important factor to consider after a diagnosis of IC or recurrent cystitis.

You may find certain foods in your diet cause your symptoms to flare up more than others. Identifying those 'triggers' and planning your meals to avoid them can help support your treatment with iAluRil® and keep symptoms at bay.

The following are some of the most common triggers to keep in mind.

- Citrus fruits like oranges and lemons
- Tomatoes
- Chocolate
- Caffeinated drinks like coffee and soda
- Carbonated drinks
- Alcohol
- Spicy foods
- Artificial sweeteners

Everyone's different, so the foods most likely to flare your symptoms will be personal to you. Using a food diary to keep track of your symptoms could help you identify what these triggers are.

Food and symptom diary

You might like to keep a daily diary to help monitor how your symptoms change according to what you've eaten. The template below is an example of how it could be structured.

Food Diary		
	Monday	Tuesday
Breakfast	Toast Jam Butter	
Lunch		
Dinner		
Snack		Chocolate biscuit
Drink		
Symptoms		
Frequency		
Urgency		
Nocturia		
Pain Score		
Total		
Scale of symptoms: 1 = no pain 10 = Extreme pain		

Try to list all the foods each day

List all the items you have had for each meal

Include all snacks; fruit, chocolate etc.

You should try and drink around 8 pints of water a day

How many times a day do you urinate?

How many times in a day do you feel the sudden urge to urinate?

How many times do you go to the toilet during the night?

How severe is your pain?
1 = No Pain
10 = Extreme

Calculate the total score from your answers here, you may start to see a trend when there is a higher score it could relate to the food or drinks you have consumed

Score your symptoms from the list below

For more information, or to download a template food diary visit www.ialuril.co.uk

Terminology

Visual Analogue Scale pain score

Visual Analogue Scale (VAS) is a simple assessment tool which measures the levels of pain experienced using a scale of 0 to 10.

Frequency

The number of times you urinate throughout the day.

Urgency

When you feel the sudden urge to urinate.

Nocturia

When you urinate at night time.

Urge Incontinence

Urge incontinence is when you urinate without meaning to. This is where you have an immediate unstoppable urge to urinate, which leads to involuntary leakage.

How Severe is Your Pain?

VAS pain score

On each Pretreatment and Course of Treatment page mark an X anywhere on the VAS Pain Scale line to show the severity of the pain that you experience on a regular basis. Where 0 is when you experience no pain and 10 is when you are experiencing the worst pain possible.

This will help monitor your pain throughout treatment.



Recording information

Record the number of times you experience any of the other symptoms (i.e., frequency, urgency, nocturia and urge incontinence) per day.

Personal Details

Name:

Date of Birth:

Address:

Telephone Number:

Contacts

Hospital Patient Number:

Hospital Telephone Number:

Hospital Department:

Specialist Nurse Telephone Number:

Other useful contacts/information:

Pretreatment

Date:

Current symptoms:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



How are your current symptoms affecting your lifestyle:

Course of Treatment

Treatment Number:	Adapter used: Y / N
Date:	
Nurse:	
Frequency:	
Urgency:	
Nocturia:	
Urge Incontinence:	
VAS Pain Score:	
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>012345678910</div>	
Duration iAluRil Was Retained Within The Bladder:	
Date of Next Appointment:	

Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



Duration iAluRil Was Retained
Within The Bladder:

Date of Next Appointment:

Course of Treatment

Treatment Number:	Adapter used: Y / N
Date:	
Nurse:	
Frequency:	
Urgency:	
Nocturia:	
Urge Incontinence:	
VAS Pain Score:	
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Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



Duration iAluRil Was Retained
Within The Bladder:

Date of Next Appointment:

Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:

0

1

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Duration iAluRil Was Retained
Within The Bladder:

Date of Next Appointment:

Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

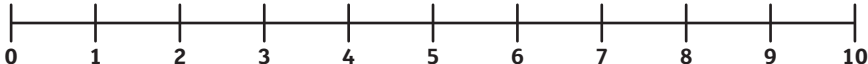
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Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



A horizontal line with vertical tick marks at intervals of 1, labeled from 0 to 10.

Duration iAluRil Was Retained
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Date of Next Appointment:

Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:

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Course of Treatment

Treatment Number:	Adapter used: Y / N
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Urge Incontinence:

VAS Pain Score:

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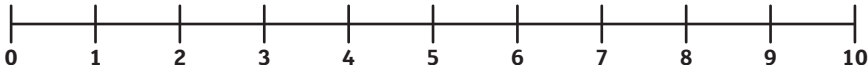
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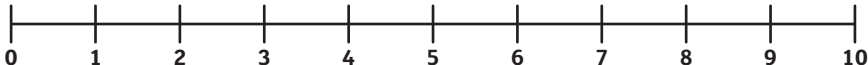
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Urge Incontinence:

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Urgency:

Nocturia:

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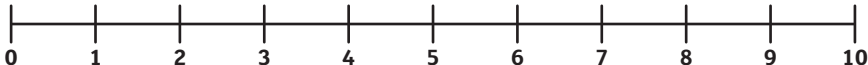
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Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



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Within The Bladder:

Date of Next Appointment:

Course of Treatment

Treatment Number:	Adapter used: Y / N
Date:	
Nurse:	
Frequency:	
Urgency:	
Nocturia:	
Urge Incontinence:	
VAS Pain Score:	
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Course of Treatment

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Course of Treatment

Treatment Number:

Adapter used: Y / N

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Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:

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Course of Treatment

Treatment Number:

Adapter used: Y / N

Date:

Nurse:

Frequency:

Urgency:

Nocturia:

Urge Incontinence:

VAS Pain Score:



Duration iAluRil Was Retained
Within The Bladder:

Date of Next Appointment:

Investigations and Results

Date:

Hospital:

Procedure:

Results:

Follow Up:

Date:

Hospital:

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Results:

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Investigations and Results

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Notes

Notes

Reporting of Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the product's package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medical device.

References: 1) <https://www.theurologyfoundation.org/professionals/healthcare-resources-and-reports/urology-resources/facts-and-figures/bladder-related-statistics> (Accessed July 2021). 2) Metts JF. Interstitial Cystitis: Urgency and Frequency Syndrome. Am. Fam. Physician 64(7): 1199-1207 (2001). 3) <https://www.webmd.com/urinary-incontinence-oab/ss/slideshow-leaky-bladder-triggers> (Accessed July 2021)

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