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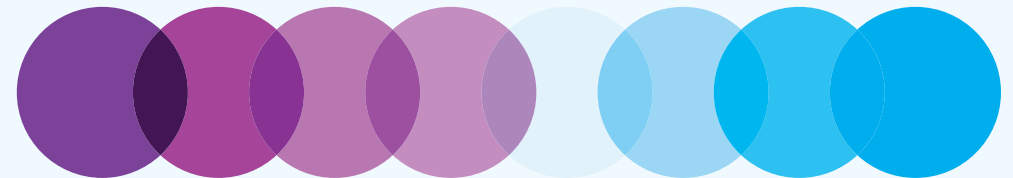
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Reporting of Side Effects

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 medicine.

iAluRil[®]
Sodium Hyaluronate | Sodium Chondroitin Sulphate | Calcium Chloride
with iAluadapter[®]



What is iAluRil®?

iAluRil is a medical device for the treatment of cases where the loss of components of the bladder lining causes chronic inflammation and infection.

iAluRil can be used to treat:

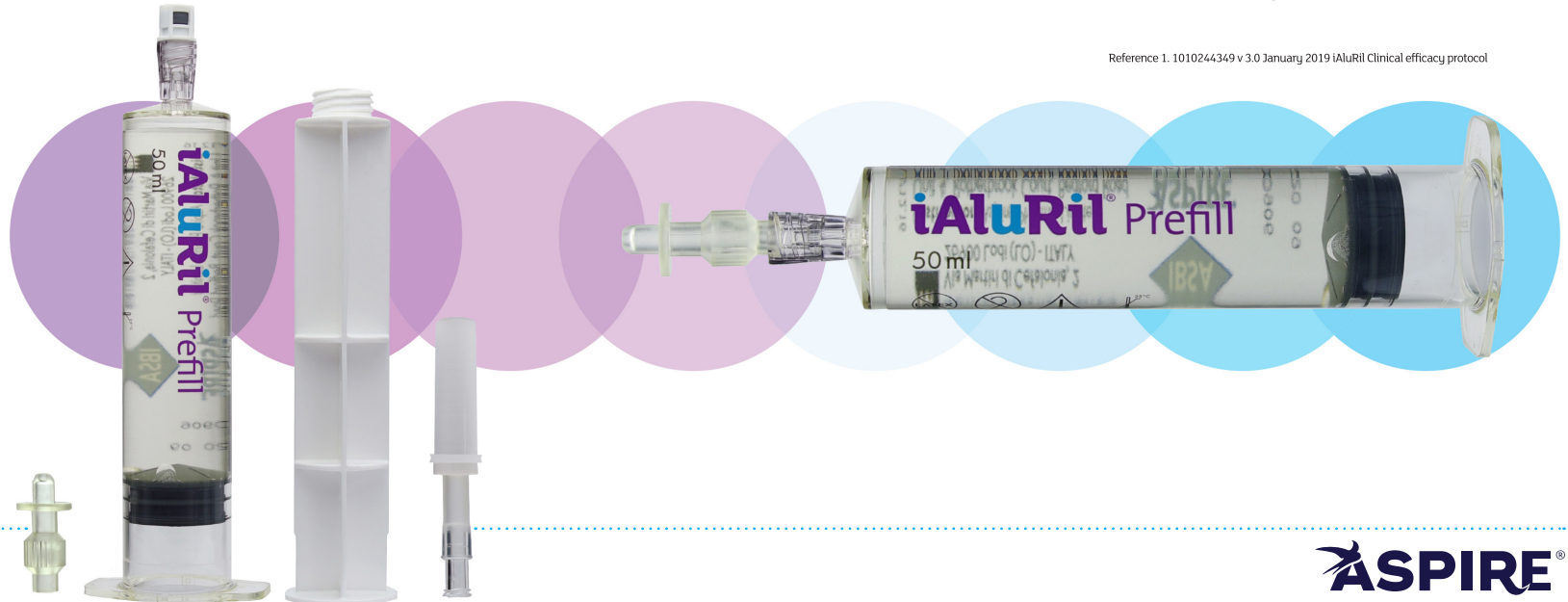
- Interstitial cystitis/painful bladder syndrome;
- Chemical cystitis – damage to the bladder lining caused by chemotherapy;
- Radiotherapy-induced cystitis – damage to the bladder lining caused by radiation to the pelvis;
- Recurrent urinary tract infections.

iAluRil works directly on the bladder lining 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), with the additional benefit of calcium chloride. By administering iAluRil directly into the bladder, these GAGs help to repair the damage to the GAG layer and restore the bladder's protective coating. Calcium chloride increases the stability of these components and their binding to the bladder wall, helping to relieve your symptoms.



How is iAluRil administered?

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

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

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 interval between instillations can be increased slowly until you are happy that the regular doses are enough to keep symptoms under control. If the symptoms reoccur, the initial course of instillations can be repeated in order to settle the symptoms down again.

Will I get any side effects?

Two of the three components of iAluRil are found naturally in your body, therefore, it is unlikely that this product will cause any side effects. 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.

Further information

If you have any questions regarding your treatment or illness, do not hesitate to discuss these with your doctor or nurse. For further information you can visit:

www.ialuril.co.uk

Alternatively you can contact Bladder Health UK, a patient support group for patients with cystitis and overactive bladder, on their national helpline (0121 702 0820) or visit their website www.bladderhealthuk.org

Reference 1. 1010244349 v 3.0 January 2019 iAluRil Clinical efficacy protocol