Introduction

Although your condition may have been diagnosed some time ago, when you begin a new treatment it’s normal to have lots of questions.

We hope this booklet will help you find the answers to a few common questions about Infllectra™.

However, if you have specific questions, your physician is usually the best person to ask. Your doctor already understands your condition and the way it affects your daily life.

You will also receive a patient information leaflet with this booklet. Please read the patient information leaflet carefully before you start using your medicine.

In this booklet you will find information on:

- What is rheumatoid arthritis?
- What Infllectra is, and how it works for adults with rheumatoid arthritis
- Some Q&As on what to expect when you start your treatment
- How to report any adverse events you may experience

In addition, your Patient Alert Card can be found on the inside back cover.

The Patient Alert Card contains important safety information you need to be aware of before and during treatment.

What is rheumatoid arthritis?

Rheumatoid arthritis (RA) is an immune-system disease that causes inflammation of the joints. RA makes your joints swell and feel stiff and painful. This can make it hard to do everyday activities, such as simple manual tasks or seeing friends and family.

Both men and women can get rheumatoid arthritis, but it is more common in women. It can start at any age, but is most likely to develop in people between the ages of 20 and 40.
**Diagnosis**

Rheumatoid arthritis can be difficult to diagnose because many conditions cause joint stiffness and inflammation.

Your doctor will have looked at your symptoms and medical history, and given you a physical exam to check your joints for any swelling, warmth and stiffness.

Blood tests may be performed to help confirm the diagnosis. An x-ray or MRI scan may be completed to determine if you have any joint damage and whether it is getting worse over time. There is no specific test that confirms a diagnosis of RA.

**Common blood tests:**

Rheumatoid factor (RF) is an antibody that eventually becomes present in the blood of most people with RA, but not all people who test positive for RF have RA.

Anti-citrullinated peptides/proteins antibodies (ACPA) are more specific for RA, and most people with RA will have a positive result to a blood test.

Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are not specific to RA, but indicate there is inflammation in your body.

A Complete Blood Count (CBC) measures your white blood cell count, which may be elevated, and your red blood cell count, to check for anaemia which is common in RA.

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**Symptoms**

You may experience some of the following symptoms, but the pattern varies between different people.

**Joint symptoms**

*Pain and/or swelling in the joints*

Rheumatoid arthritis generally affects the hands, wrists, knees or feet, but other joints can be affected too. Pain usually affects the joints on both sides of the body equally. It can be described as a throbbing and aching sort of pain.

*Joint stiffness*

You may feel stiff. Some people find the stiffness is worse when they first get up in the morning. It usually lasts longer than 30 minutes, and will ease as they get moving.

*Warmth and redness*

As the lining of your affected joints becomes inflamed, your joints may feel warm, tender and stiff.

**Loss of energy**

You may feel fatigued and tired.

**Flu-like symptoms**

Some people feel hot, sweaty and generally unwell, as if they have the flu, and some people may have occasional fevers.

**Flare-ups**

Symptoms vary from person to person and may change over time. Many people have mild symptoms that occasionally become more severe. There is often no particular reason for symptoms to become worse. Flare-ups are impossible to predict. This can upset people’s plans and make life difficult.

**Less common symptoms**

Inflammation can affect other areas of your body, such as your tear glands, salivary glands, the lining of your heart and lungs and your blood vessels.
Causes

Auto-immune disease
Your immune system’s job is to defend your body by fighting infection. Sometimes, the immune system starts to attack the cells lining your joints instead. Researchers don’t know what triggers the change.

The attack on the lining of your joints causes uncontrolled inflammation. The symptoms are a result of the inflammation. If it is left untreated, it can eventually damage your joints. That is why it is a good idea to talk to your doctor as soon as you can.

Lifestyle factors
Cigarette smoking is a recognised factor that increases the risk of developing rheumatoid arthritis. There is also some evidence that cigarette smoking increases the likelihood that RA will be severe when it occurs.

People with RA often report that they have experienced periods of stress or trauma before their RA started. Stressful “life events” (e.g., divorce, accidents and grief) are more common in people with RA in the 6 months before their diagnosis compared with the general population.

Family history
Rheumatoid arthritis tends to run in families. So if a close relative has it, you may be more likely to develop it too.

Outlook

A progressive disease
There is currently no cure, but your doctor can give you treatment to help slow down the progression and minimise any joint damage. This is important because the longer you have rheumatoid arthritis, the more likely it is to cause damage to your joints.

The earlier rheumatoid arthritis is diagnosed and treated, the more effective the treatment will be.
Treatment
There are several types of treatments that you may be prescribed, including:

Non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids
- Can relieve pain and swelling in your joints; however, they will not slow down progression

Disease-modifying anti-rheumatic drugs (DMARDs)
- Can substantially reduce symptoms and slow down progression, preserving joint structure and function
- Drugs in this class include methotrexate, hydroxychloroquine, sulfasalazine and leflunomide

Biological treatments – a newer form of DMARDs
- They include TNF-alpha inhibitors
- Can help to ease symptoms and slow down progression
- Biological treatments are not suitable for everyone and are typically reserved for patients with severe symptoms who have not responded to other treatments

Inflectra™ for adults with rheumatoid arthritis

What is my treatment for?
Inflectra is used to treat several different inflammatory conditions, one of which is rheumatoid arthritis.

If you have rheumatoid arthritis, you may have been given other medicines already. If you did not respond well enough to these medicines, you may be given Inflectra.

Inflectra is given in combination with another medicine called methotrexate, which acts on the immune system. Inflectra may help to control your rheumatoid arthritis and improve your wellbeing.

What will it do?
Inflectra is usually used when other medicines or treatments have failed.

The aim of therapy is to reduce the signs and symptoms of your rheumatoid arthritis and to improve your physical function. This will help you to continue being active in the future. It can also slow down the damage in your joints.
How does Inflectra™ work?
Rheumatoid arthritis can affect people in different ways, so your symptoms will be personal to you. But no matter how rheumatoid arthritis affects you, Inflectra works to reduce the effects of inflammation in your body.

Normally, your immune system protects you from being harmed by bacteria, viruses and other substances. In some people, the immune system becomes overactive causing inflammation, which can damage tissues in the body.

Having an overactive immune system can cause your body to produce high levels of a chemical messenger called TNF-alpha (which stands for ‘tumour necrosis factor’ alpha). TNF-alpha is involved in causing inflammation. In people with rheumatoid arthritis, TNF-alpha is overproduced. This causes inflammation and damage to the bones and the cartilage in their joints.

Inflectra works by attaching to TNF-alpha and blocking its action (it is called a ‘TNF blocker’). This can reduce inflammation and other symptoms of the disease. The active substance in Inflectra, infliximab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body.

What can my friends and family do to help?
Your family and friends can provide strong support. Communicating with each other openly and honestly about feelings and fears can help. It also helps if your family understands your disease and how it is being treated. This can help everyone in the family work together to make life as good as possible for you.

Many people ask a friend or family member to come with them to their appointments. It can be useful to have someone else to listen, take notes and offer support.

How can I help myself?
Eating healthily, getting enough rest and minimising stress can all help your body cope with treatment.

Getting in touch with others with a similar condition via patient support groups can also be comforting.
How is Inflectra™ administered?
You will normally have to visit a hospital or a clinic to receive your treatment.
It is slowly injected over 2 hours into a vein – usually in your arm. This is called an ‘intravenous infusion’ or drip.
After your third treatment, your doctor may decide to give your intravenous infusion over a 1 hour period.
You will be monitored for any reactions while you are given your treatment, and also for at least 1-2 hours afterwards.
It can help to take something along to keep yourself occupied when you are receiving infusions such as books, magazines, a tablet, computer, handheld game console or a friend to talk to.

How often will I receive treatment?
When you start treatment with Inflectra for rheumatoid arthritis, you will normally receive an initial dose, followed by a dose 2 weeks later, and another dose 6 weeks after the first.
How often it is repeated after that depends on your response to the treatment.

Are there any side effects with Inflectra™?
Like all medicines, Inflectra can cause side effects, although not everybody has them. Most side effects are mild to moderate. However some patients may experience serious side effects and may require treatment. Side effects may also occur after your treatment with Inflectra has stopped.
If you experience any side effects, talk to your doctor.

Tell your doctor straight away if you notice any of the following:

- **Signs of an allergic reaction** such as swelling of your face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles within 2 hours of your injection or later; or pain in the muscles, fever, joint or jaw pain, sore throat or headache up to 12 days after your injection

- **Signs of a heart problem** such as shortness of breath, swelling of your feet or changes in your heartbeat

- **Signs of infection** (including TB) such as fever, feeling tired, (persistent) cough, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems or burning when urinating

- **Signs of a lung problem** such as coughing, breathing difficulties or tightness in the chest

- **Signs of a nervous system problem** (including eye problems) such as fits, tingling or numbness in any part of your body, weakness in arms or legs, changes in eyesight such as double vision or other eye problems
- **Signs of a liver problem** such as yellowing of the skin or eyes, dark-brown coloured urine or pain in the upper right side of the stomach area, fever
- **Signs of an immune system disorder** called lupus such as joint pain or a rash on cheeks or arms that is sensitive to the sun
- **Signs of a low blood count** such as persistent fever, bleeding or bruising more easily or looking pale

Please read the patient information leaflet provided with this booklet for more detailed information on side effects.

To reduce the risk of infusion-related reactions, you may be given other medicines before or during treatment, or the infusion time may be slowed down.

Your doctor will also give you a Patient Alert Card (see opposite page), which contains important safety information you need to be aware of before and during treatment. It prompts you to tell your doctor straight away if you notice signs of a heart problem or an infection, even if it is a minor one.

**Report possible side effects**

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See [www.hpра.ie/homepage/about-us/report-an-issue](http://www.hpра.ie/homepage/about-us/report-an-issue) for how to report side effects.

Side effects should also be reported to Hospira Medical Information Direct Line: +44 (0) 1926 834 400.

You should also discuss any side effects you are experiencing with your physician.

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**Patient Alert Card**

Your Patient Alert Card contains important safety information you need to be aware of before and during Inflectra™ treatment. It prompts you to tell your doctor straight away if you notice signs of a heart problem or an infection, even if it is a minor one.

You should keep this card with you for 4 months after your last dose of Inflectra as side effects may occur a long time after your last dose.

It is important that you and your doctor record the brand name and batch number of your medication.

You should show this card to any doctor involved in your treatment.

Please also carefully read the patient information leaflet provided with this booklet before you start to use your medicine.