

PATIENT INFORMATION ON

INFLIXIMAB

(Brand name: Remicade)

(Biosimilar brand names: Flixceli, Emisima, Inflectra, Jaximab, Remsima, Renflexis)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **what are the possible side effects**
- **what tests you will have to monitor your condition**
- **other precautions you should take while you are taking infliximab.**

Please read it carefully and discuss it with your specialist/GP.

Important things to remember

- While taking infliximab you must see your specialist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop infliximab for any reason you must contact your specialist. Failure to do so may mean that your continued treatment will no longer be subsidised.
- If you are worried about any side effects you should contact your specialist as soon as possible.
- It is important to tell your specialist if you have had cancer or if you develop cancer while you are taking infliximab.
- If you are taking infliximab and plan to become pregnant you must discuss the timing with your specialist/GP.

For more information about ANKYLOSING SPONDYLITIS and other inflammatory conditions see Arthritis Australia's website: www.arthritisaustralia.com.au

What is infliximab?

Infliximab (brand name: Remicade®) belongs to a group of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs)**.

bDMARDs have now been given to over a million people worldwide since their initial use in the late 1990s. Recently biosimilar infliximab products have become available. A biosimilar is a version of infliximab that has been shown to have similar safety and effectiveness as the original brand.

These medicines block natural substances, produced by arthritic tissues, called cytokines. These substances are found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

The increased levels of cytokines cause inflammation, which results in symptoms of pain, joint swelling and stiffness, and can lead to joint damage.

By blocking the cytokine called Tumour Necrosis Factor (TNF), infliximab reduces inflammation, lessens the symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

Unlike many standard antirheumatic drugs (DMARDs), infliximab works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 4 weeks of treatment.

Stopping infliximab

If infliximab treatment is stopped or not received at the recommended intervals there is a risk that your condition may worsen. Continue with your treatment unless advised by your specialist/GP or unless side effects develop (see *Side effects*). If you stop infliximab for any reason you **must** contact your specialist/GP. Failure to do so may mean that your continued treatment may no longer be subsidised.

Brands of infliximab

You should not switch between different brands of infliximab unless advised to do so by your specialist. Make sure you are given the same brand each time. If you need to change brands, your specialist will advise you to and will monitor for side effects like when you first started treatment.

How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs:

- Infliximab will only be given if your disease is active and if standard treatments have been unsuccessful.
- It will only be continued if it helps your condition. This will be assessed between 12 and 16 weeks after the start of treatment.
- Blood tests will be required during your treatment to monitor your condition and to determine the effectiveness of treatment and for side effects.
- The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your specialist will determine the frequency of tests required.

How is infliximab given?

Infliximab is given as a drip (infusion) into the vein. The infusion normally takes 1 to 4 hours. You will need to stay for at least an hour after the infusion to make sure you don't have any immediate side effects.

The second dose is given 2 weeks after the first and the third dose 4 weeks after the second. The timing of subsequent doses depends on the disease being treated and is usually every 6 to 8 weeks.

Infliximab is usually given in combination with the DMARD methotrexate.

Sometimes a cortisone medication may be used as part of a premedication to reduce side effects (see *Are there any side effects*).

What is the dosage?

The dosage is based on body weight so each person's dose will vary.

Can other medicines be taken with infliximab?

Infliximab may be safely used with other arthritis medicines including:

- other DMARDs such as methotrexate
- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen)
- simple pain medicines such as paracetamol.

Infliximab cannot be used with other bDMARDs. There are separate information sheets available on the ARA website for the medicines mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Contact your specialist/GP if you have any concerns about possible side effects. Many side effects disappear when infliximab treatment is stopped.

Most common possible side effects

- Side effects can occur during the infusion itself. These may include *fever or chills, itch, chest pain, shortness of breath or changes in blood pressure*. These effects are more likely to occur during the first or second infusion and can usually be reduced by giving steroids, anti-histamines and paracetamol before the treatment.
- *Headaches, cough and stomach and bowel discomfort* may also occur.
- As infliximab affects the immune system, *mild infections*, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment with infliximab may need to be temporarily stopped so contact your specialist/GP for advice.

Less common or rare possible side effects

- *Serious infections* such as tuberculosis (TB) are seen rarely, and screening for TB is

needed before treatment begins (see *Precautions*).

- Rarely infliximab may cause an *allergic reaction* with itchy, red skin or a rash or a feeling of tightness in the chest and difficulty breathing.
- Side effects involving the nerves, such as *inflammation of the nerve to the eye*, may also occur rarely, causing changes in vision or sensation.
- Very rarely '*drug-induced lupus*' has occurred with symptoms of rash, fever and increased joint pain.
- It is still unclear from research if there is an increased risk of cancer due to infliximab treatment (see *Precautions*).

What precautions are necessary?

Infections

- If you have an active infection of any kind treatment with infliximab will not be given until the infection is treated successfully.
- Infliximab will not be given if you have active untreated tuberculosis (TB) or HIV (AIDS) infection as it is likely to make these conditions worse.
- If you have latent (inactive) TB preventative anti-TB treatment will be started at least 4 weeks before infliximab. The anti-TB treatment will usually need to be taken for a total of 9 months.
- Hepatitis B or C infection may not necessarily exclude treatment with infliximab.
- Because of the risks associated with infection the following tests may be conducted before commencing treatment with infliximab:
 - blood tests for hepatitis B and C
 - chest x-ray and a test for tuberculosis (TB)
 - HIV tests are required for those who are at risk of this infection.

Precautions with other diseases

- People with multiple sclerosis should not be treated with infliximab, or other anti-TNF therapies, due to the possible effects on the nerves.
- People with moderate to severe heart failure may not be treated with infliximab as the medicine can make heart failure worse.
- People with systemic lupus erythematosus (lupus/SLE) are not usually given infliximab but each case will be assessed individually.

Use with other medicines

- Infliximab can interact with other medicines. You should tell your specialist/GP (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.
- You should also tell all other health professionals that you see that you are taking infliximab.
- Infliximab does not increase the risk of side effects from low dose aspirin (taken for prevention of heart attack and strokes).
- The simple pain reliever paracetamol and combined pain medicines such as Panadeine and Panadeine Forte can be used while you are receiving infliximab.

Vaccines

- If you are on infliximab it is recommended you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), OPV (oral polio virus), BCG (Bacillus Calmette Guerin) or yellow fever. Talk with your specialist before receiving any vaccines.
- Pneumovax and the combined yearly seasonal flu vaccinations are safe and recommended to reduce your risk of those infections.

Surgery

- If you require surgery for any reason treatment with infliximab will be stopped before surgery. It will be restarted again after the operation at a time determined by your surgeon and specialist (usually once the wound is healed and if there is no infection present).

Cancer risk

- Lymphoma, a cancer of lymph glands, is found more commonly in patients with severe active rheumatoid arthritis than in the general population. Studies are in progress to see if treatment with infliximab changes this. To date there is no evidence to suggest that this medicine increases lymphoma.
- If cancer has been previously treated and cured it is unclear whether a TNF-bDMARD such as infliximab can be used safely. An interval of 5 years is normally recommended between cure of a cancer and starting TNF-bDMARDs.
- For general cancer prevention stopping smoking and taking skin cancer prevention

measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.

- Talk to your specialist/GP if you have any concerns about issues relating to cancer risk.

Use with alcohol

- You may drink alcohol while taking infliximab. However, if you are also taking methotrexate you should be cautious about your alcohol intake.
- It is not known precisely what level of drinking is safe when on methotrexate, however there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Use in pregnancy and when breastfeeding

- It is important to discuss with your doctor if you are planning a pregnancy while on infliximab.
- It may be used in pregnancy and in men trying to father a child.
- If infliximab is continued beyond 4 months of pregnancy it may increase the risk of infection in the newborn and live vaccines such as Rota virus should not be given before the baby is 7 months old.
- There is only limited information regarding infliximab in breast milk and while small

amounts may occur, it does not appear to be harmful.

How to store infliximab

- Store infliximab in a cool, dry place, away from direct heat and light (e.g. not in the bathroom).
- Keep all medicines out of reach of children.

<p style="text-align: center;">Questions?</p> <p>If you have any questions or concerns write them down and discuss them with your specialist/GP.</p>	<p style="text-align: center;">Your specialist/GP's contact details</p> <p>If you are taking infliximab you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.</p>
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The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.