PATIENT INFORMATION ON INFLIXIMAB

[In-FLIX-i-mab]

Brand name: Remicade Biosimilar brand names: Inflectra, Renflexis

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

- how you should take your medication •
- 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 doctor.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist.
- It is important to tell your rheumatologist if • you have a new serious illness such as a serious infection, cancer or heart failure.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop infliximab for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must discuss the timing with your rheumatologist

For more information about inflammatory conditions associated with arthritis. see Arthritis Australia's website: www.arthritisaustralia.com.au

What is infliximab?

Infliximab belongs to a class of medications called biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs). Specifically, it is a TNF inhibitor.

bDMARDs have now been given to over a million people worldwide since their first use in the late 1990s

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

They 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 lessens inflammation, pain symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

You may notice lessening of joint swelling, pain and stiffness, often within the first 8 weeks of starting.

Stopping infliximab

If you stop or delay your infliximab treatment, you may worsen again. Keep on your treatment, unless told by your rheumatologist to stop or unless side effects occur (see Side effects).

If you stop infliximab for any reason, you **must** contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.

Brands of infliximab

There are also biosimilar infliximab medications. A biosimilar is a version of infliximab that has been shown to have similar benefits and safety as the original brand. You should not switch between different brands of infliximab unless told to do so by your rheumatologist.



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Make sure you are given the same brand each time. If you need to change brands, your rheumatologist will advise you and will check for side effects.

How will you be checked while on infliximab?

- Medications like infliximab are very expensive and highly funded by Medicare. Certain conditions must be met to receive it.
- Infliximab will only be given if your disease is active and if standard treatments have not worked.
- It will only be continued if it helps your condition. This must be checked between 12 and 16 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and decide if the treatment is working.
- How often you have blood tests will depend on what other medications you are taking and what other illnesses you might have. Your rheumatologist will advise on this.

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 do not 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 remaining doses depends on the disease being treated and is often every 6 to 8 weeks.

Infliximab is often given in combination with the DMARD methotrexate.

Sometimes a cortisone medication may be used as part of a premedication to lessen 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 medications be taken with infliximab?

Infliximab may be safely used with other arthritis medications including:

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

• simple pain medications such as paracetamol.

Infliximab cannot be used with other bDMARDs.

There are separate information sheets on the ARA website for the medications mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Contact your rheumatologist if you have any concerns about possible side effects. Many side effects go away when infliximab 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 often be lessened by giving steroids, antihistamines and paracetamol before the treatment.
- Headaches, cough, stomach and bowel discomfort may also occur.
- As infliximab affects the immune system, mild infections, mainly the upper respiratory tract (e.g. colds, sinusitis) may occur more often. Treatment with infliximab may need to be briefly stopped for a serious infection so contact your rheumatologist 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.
- Rarely, infliximab may cause an allergic reaction with itchy, red skin or a rash or a feeling of tightness in the chest and trouble 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.
- Annual skin checks are suggested with any medications that can suppress the immune system as there is a slight increase in risk in skin cancers. To date research and use over 20 years, have not shown an increase in risk of other cancers.

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What precautions are necessary? *Infections*

- If you have a current infection of any kind treatment with infliximab should not be given until the infection is treated.
- You will need some blood tests and a chest X-Ray to exclude some chronic infections before your first bDMARD.

Use with other medical conditions

Worsening may occur of the following conditions:

- multiple sclerosis.
- moderate to severe heart failure.
- systemic lupus erythematosus (lupus/SLE) People with SLE are not often given golimumab but each case will be assessed whether safe by your rheumatologist.

Use with other medications

 Infliximab can interact with other medications. You should tell all your doctors about all medications you are taking or plan to take. This includes over the counter or herbal/naturopathic medications.

Vaccines

- If you are taking infliximab you should not be immunised with 'live' vaccines such as
- MMR (measles, mumps and rubella), Varicella vaccine (Chicken pox/shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are safe and encouraged.

For more information on vaccination including the COVID-19 vaccination go to the ARA website; <u>https://rheumatology.org.au/</u> patients, medication information, vaccinations.

Surgery

 If you need surgery for any reason, infliximab should be stopped before surgery. It can start again after the operation at a time decided by your surgeon and rheumatologist, (often once the wound has healed as long as there is no infection).

Use with alcohol

 You may drink alcohol while taking infliximab. If you are also taking methotrexate you should be cautious about how much alcohol you drink.

Use in pregnancy and when breastfeeding

- It is important to discuss with you 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 kept going beyond 4 months of pregnancy it may increase the risk of infection in the newborn when live vaccines may be due.
- The rotavirus vaccine should be given within the first six months of life. MMR may be given at 6 months.
- There is only limited information regarding infliximab in breast milk and while small amounts may occur, it does not seem to be harmful.

More detailed information is available at: <u>https://rheumatology.org.au/For-</u> <u>Patients/Pregnancy-Information</u>

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

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 medications 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 medication. 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.

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