PATIENT INFORMATION ON

TOFACITINIB

(Brand name: Xeljanz®)

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 must have to monitor your condition and to detect unwanted effects
- other precautions you should take when you are taking tofacitinib.

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking tofacitinib you must see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects. You will require regular review for application for subsidised medication through the PBSA as advised by your treating rheumatologist.
- If you stop tofacitinib for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- If you are worried about any possible side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer while you are taking tofacitinib.
- If you are taking tofacitinib and plan to become pregnant you must discuss the timing with your doctor.

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

What is tofacitinib?

Tofacitinib (brand name: Xeljanz) belongs to a class of medicines called non-**biological disease modifying antirheumatic drugs (non-biological DMARDs or nbDMARDs).**

Tofacitinib is a Janus Kinase (JAK) inhibitor. JAK inhibitors work by reducing immune and inflammatory processes in rheumatoid arthritis. Tofacitinib is available as a tablet and does not have to be injected.

What benefit can you expect from your treatment?

Unlike standard antirheumatic drugs (DMARDs), tofacitinib works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 2 to 4 weeks of treatment.

Stopping tofacitinib

If you stop tofacitinib treatment for more than a few weeks there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop (see *Side effects*).

If you stop tofacitinib for any reason you **must** contact your doctor. Failure to do so may mean that your continued treatment may no longer be subsidised.

How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs:

- Tofacitinib will only be given if your disease is active and if standard treatments have been unsuccessful.
- It will not be continued unless it helps your condition. This will be assessed at about 12 weeks after the start of treatment.
- Blood tests will be required during your treatment to monitor your condition, possible side effects and to determine the effectiveness of treatment.

- The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.

How is tofacitinib taken?

Tofacitinib is taken by mouth in tablet form.

What is the dosage?

The usual dose for adults with rheumatoid arthritis is one 5mg tablet twice daily.

Can other medicines be taken with tofacitinib?

Tofacitinib may be used with other arthritis medicines including:

- Other Disease Modifying AntiRheumatic Drugs (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.

Tofacitinib should not be used with other bDMARDs.

There are separate information sheets for the medicines mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you are concerned about possible side effects. Many side effects disappear when tofacitinib treatment is stopped.

Most common possible side effects

- As tofacitinib affects the immune system, infections may occur more frequently than usual. There is an increased incidence of a painful rash called shingles. Treatment with tofacitinib may need to be stopped for a while if you develop infection, so contact your doctor for advice. Symptoms of an infection include fever, sweating or chills, muscle aches, cough, shortness of breath, warm or red skin or sores on your body, burning feeling when urinating or urinating more often than normal.
- Upper respiratory infections, headaches, nasopharyngitis (stuffy nose and throat) and diarrhoea have been noted to occur in about 2% of patients treated.

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*).
- *Lipids* (cholesterol): Increases in lipid levels have been noted in some patients when taking tofacitinib. This effect is seen early in treatment and it is recommended that your lipids are checked at 8 weeks.
- *Liver function tests:* there is an increased risk of liver function abnormalities. It is recommended to have regular liver function tests.

Tell your doctor or pharmacist immediately of any of side effects you experience.

What precautions are necessary

Infections

- If you have an active infection of any kind, treatment with tofacitinib will not be started until the infection is treated successfully.
- If you have latent (inactive) TB, preventative anti-TB treatment will be started at least 4 weeks before tofacitinib. The anti-TB treatment will usually need to be taken for 9 months.
- Hepatitis B or C infection may not necessarily exclude treatment.

Precautions with other diseases

- Tofacitinib should be used with caution in patients with slow heart rates (slow pulse) and who use medications that can cause heart block. Care should be taken in patients with a history of angina, heart attack or heart failure.
- The dose of your medication may need to be adjusted if you have kidney or liver disease.
- Sometimes tofacitinib may cause an ulcer in your stomach or gut, especially if this has been a problem in the past. Tell your doctor straight away if you have stomach ache or pain that won't go away or a change in bowel habits.

Use with other medicines

- Some medicines can affect tofacitinib or may affect how well it works. It is noted to interact with anti-fungal therapy such as ketoconazole, some antibiotics such as rifampicin and some heart medicines Always tell your doctor (including your general practitioner rheumatologist and others) about all medicines you are taking or plan to take. This includes all over the counter, herbal or naturopathic treatments.

- You should also mention your treatment when you see other health professionals.

Vaccines

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

Surgery

- If you require surgery for any reason, treatment with tofacitinib should be stopped one week before surgery. It will be restarted again after the operation at a time agreed by your surgeon and rheumatologist (usually when the wound is healed).

Cancer risk

- It is still unclear if there is an increased risk of cancer due to tofacitinib treatment. Rates of cancer occur at the same rate as in patients on other bDMARDs. Regular skin monitoring is recommended to detect melanoma and non-melanoma skin cancers.
- Talk to your doctor if you have any concerns about issues relating to cancer risk.

Use with alcohol

- You may drink alcohol while taking tofacitinib. However, if you are also taking methotrexate you should be particularly cautious about your alcohol intake.

Use in pregnancy and when breastfeeding

- Tofacitinib should not be used during pregnancy. Pre-pregnancy planning should be discussed with your treating doctor.
- Do not breastfeed if you are taking tofacitinib as it is uncertain how much of the drug might be excreted in breastmilk.
- More detailed information is available at https://rheumatology.org.au/gps/documents/ARAPregnancyPrescribingGuidanceupdateApr19.pdf

How to store tofacitinib

- Tofacitinib tablets should be kept in a cool dry place where the temperature stays below 30^{o}C.
- Keep all medicines out of reach of children.

Disposal

- If your doctor tells you to stop taking your medicine, or if the expiry date has passed, return any unused tofacitinib tablets to your pharmacy.
- Do not dispose of tofacitinib tablets via wastewater or household waste.

Questions?

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

Your doctor's contact details

If you are taking tofacitinib you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects

How to help us help you
Sign up to the ARAD project now!

The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems.
The best way to get this information is from you!
Contact us in any of the following ways:

Email: **ARAD@monash.edu**
Telephone: **03 9508 3424**
Visit our website: www.ARAD.org.au