

# PATIENT INFORMATION ON TOFACITINIB

[Toe-FAH-sit-in-ib]

Brand name: **Xeljanz®**

This information sheet was written 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 taking tofacitinib.**

Please read it carefully and discuss it with your doctor. This information sheet is not intended to replace the product information or discussion with your rheumatologist.

## 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, heart failure or stroke, so that your arthritis treatment can be reviewed.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop tofacitinib for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- Patients commencing tofacitinib should ensure they have close monitoring of their cardiovascular risk factors, including blood pressure and cholesterol with their local doctor.
- If you are taking tofacitinib and plan to become pregnant you must discuss the timing with your rheumatologist.

## TGA BOXED WARNING

Tofacitinib should only be used if no suitable treatment alternatives are available in patients:

- With a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers).
- With malignancy risk factors (e.g. current malignancy or history of malignancy).
- Who are 65 years of age and older.

For more information about **RHEUMATOID ARTHRITIS** and other inflammatory conditions see Arthritis Australia's website: [www.arthritisaustralia.com.au](http://www.arthritisaustralia.com.au)

## What is tofacitinib?

Tofacitinib (brand name: Xeljanz®) is a tablet that belongs to a class of medications called Janus Kinase (JAK) inhibitors. JAK inhibitors work by blocking signals involved in inflammation. Blocking these signals in rheumatoid arthritis and other inflammatory conditions reduces pain, stiffness, swelling and damage in the joints.

## What benefit can you expect from your treatment?

You may notice some relief of joint swelling, pain and stiffness within the first 2 to 4 weeks of treatment, though it can take up to 3 months to improve.

The benefits of continuing tofacitinib will be reviewed at each clinic appointment and it is important you advise your treating rheumatologist of any new medical conditions at each visit.

## Stopping tofacitinib

If you stop or delay your tofacitinib treatment, your disease may get worse. Keep taking your treatment, unless advised by your rheumatologist to stop or unless serious side effects occur (see Side effects).

If you stop tofacitinib for any reason you must contact your rheumatologist. Failure to do so

may mean that your treatment may no longer be funded.

### How will you be checked while on tofacitinib?

- Tofacitinib will only be given if your disease is active and if standard treatments have not worked.
- Tofacitinib will only be continued if it helps your condition. This will be checked around 12 weeks after the start of treatment.
- Blood tests are needed during your treatment to monitor for side effects and to assess 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 have. Your rheumatologist will advise on this.

### How is tofacitinib taken?

Tofacitinib is taken by mouth in tablet form. The tablet should be swallowed whole do not crush, break or chew the tablet.

### When should it be taken?

Take this medication with a full glass of water at the same time each day. It can be taken with or without food.

If you miss a dose: Take a dose as soon as you remember. If it is almost time for your next dose, wait until then and take a regular dose. Do not take extra medication to make up for a missed dose.

### What is the dosage?

The usual dose for adults with rheumatoid arthritis and other inflammatory conditions is 5mg taken twice daily.

### Can other medications be taken with tofacitinib?

This medication may be used alone or with other arthritis medications including:

- Other disease modifying anti rheumatic drugs (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.
- There may be some instances where these medications may not be right for you, always check with your doctor prior to taking any of these medications.

Tofacitinib cannot be used with other biologic DMARDs or targeted synthetic DMARDs (such

as baricitinib, upadacitinib, etanercept and adalimumab).

### Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you notice side effects that you think are caused by this medication. Many side effects disappear when tofacitinib treatment is stopped.

### Most common side effects

The most common side effects reported are mild upper respiratory tract infections (common cold, sinus infections), nausea, cough, and fever. Infections may need treatment and tofacitinib may need to be stopped for a while if you develop infection, so it is important to contact your doctor for advice.

### Less common or rare side effects

- Blood clots in the veins of the legs, lungs and arteries are possible in some people taking tofacitinib. This can happen more often in patients with an inflammatory condition. Other risk factors including heart disease will be assessed by your doctor.
- Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins.
- Increases in cholesterol levels occur in some patients when taking tofacitinib. This will be monitored using blood tests.
- Changes in liver function can occur, it is recommended to have regular liver function tests to monitor this.
- Tofacitinib increases the risk of getting shingles. If you get a painful skin rash with blisters inform your doctor immediately. Vaccination for shingles should be discussed with your rheumatologist before starting treatment.
- Tofacitinib may increase the chance of bowel perforation, although this is rare.
- People with rheumatoid arthritis and other inflammatory conditions are at increased risk of lymphoma and some other cancers. Medications that change your immune system like tofacitinib may increase this risk.
- Skin cancers have been reported in people taking tofacitinib and yearly skin checks are recommended.
- it is recommended that patients remain up to date with their age recommended cancer

screens such as mammogram and bowel cancer screening.

- If you experience any side effects, please inform your doctor or pharmacist promptly.



## 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.

### Cardiovascular risk

People with rheumatoid arthritis and other inflammatory conditions have an increased risk of cardiovascular disorders. Recent reports have associated this medication and other JAK inhibitors with an increased risk of heart related events. Ensure your doctor is aware of any pre-existing risk factors (e.g. high blood pressure, high cholesterol, smoking status) so they can be appropriately managed.

### Use with other medications

Some medications may not be used with tofacitinib as it may change their effectiveness and how well tofacitinib may work for you.

Medications that may change how tofacitinib works include:

- Antifungals & antibiotics including ketoconazole, itraconazole, posaconazole or voriconazole, clarithromycin, rifampicin and phenytoin.
- Some medications may increase your risk of infection including those used to suppress your immune system including phenytoin, azathioprine, ciclosporin and tacrolimus.
- Other medications may require additional review and monitoring as they may increase the risk of side effects when taking tofacitinib including: NSAIDs, opioids and corticosteroids.

This list is not exhaustive. You should inform your doctor and pharmacist of all of the medications you are taking or plan to take. This includes over the counter or herbal/naturopathic medications to see if these affect tofacitinib.

### Use with alcohol

You may drink alcohol while taking tofacitinib. However, if you are also taking methotrexate you should be cautious about how much alcohol you drink.

### Vaccines

If you are taking tofacitinib you should not be immunised with 'live' vaccines such as:

- MMR (measles, mumps and rubella)
- Varicella (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 encouraged.

For more information on vaccination including the COVID-19 vaccination go to <https://rheumatology.org.au/For-Patients/Adult-Medication-Information/Vaccinations-in-Rheumatology>

### 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.

### Use in pregnancy and when breastfeeding

- It is important to inform your doctor if you are planning a pregnancy while on tofacitinib.
- Tofacitinib should not be used during pregnancy. Women of childbearing potential should use effective birth control both during treatment and for at least 4 weeks after final dose of tofacitinib.
- 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/For-Patients/Pregnancy-Information>

### How to store tofacitinib

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



### **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.

This Information Sheet has been prepared using materials obtained from various sources which have been reviewed by the Australian Rheumatology Association (ARA). It contains general information only and does not contain a complete or definitive statement of all possible uses, actions, precautions, side effects or interactions of the medicines referenced. This information is not intended as medical advice for individual conditions nor for making an individual assessment of the risks and benefits of taking a particular medicine. Decisions regarding the assessment and treatment of patients are the sole responsibility of the treating medical professional, exercising their own clinical judgment and taking into account all of the circumstances and the medical history of the individual patient.

ARA has used all reasonable endeavours to ensure the information on which this Information Sheet is based is accurate and up to date. However, the ARA accepts no responsibility or liability for the accuracy, currency, reliability and/or completeness of the information contained in this Information Sheet. To the maximum extent permitted by law, the ARA expressly disclaims any liability for any injury, loss, harm or damage arising from or in connection with use of and reliance on the information contained in this Information Sheet.

This information sheet is copyright and may be reproduced in its entirety but may not be altered without prior written permission from the ARA.

Please consider the environment before printing this resource.

