

Tofacitinib Patient Information



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TOFACITINIB (toe-fa-SIT-i-nib)

Patient Information Leaflet

Brand Name: Xeljanz®

What is Tofacitinib?



Tofacitinib is a medication that belongs to a class of drugs called Janus kinase (JAK) inhibitors. It works by blocking specific enzymes (JAK1 and JAK3) that play an important role in the inflammation process. By inhibiting these enzymes, tofacitinib helps reduce inflammation in the body.

Tofacitinib is a tablet that is taken by mouth. It is a targeted synthetic small molecule, which means it is chemically manufactured rather than being derived from living cells like biologic medications.

What is Tofacitinib used for?

Tofacitinib is approved in Australia for:

- Moderate to severe ulcerative colitis in adults
- Moderate to severe rheumatoid arthritis in adults
- Active psoriatic arthritis in adults
- Polyarticular juvenile idiopathic arthritis in patients 2 years and older

For ulcerative colitis, tofacitinib is typically prescribed when other treatments such as corticosteroids, immunomodulators, or biologic therapies have not been effective or have caused significant side effects.

How is Tofacitinib taken?

Tofacitinib comes as immediate-release tablets and extended-release tablets.

Standard dosing for ulcerative colitis:

- **Induction phase:** 10mg twice daily for 8-16 weeks
- **Maintenance phase:**
 - 5mg twice daily (standard maintenance dose)

- 10mg twice daily may be used in some patients who do not achieve adequate therapeutic benefit at 5mg twice daily (as determined by your doctor)

Tofacitinib tablets can be taken with or without food. The extended-release tablets should be swallowed whole, and not crushed, split, or chewed.

How long does Tofacitinib take to work?

The time to experience benefits from tofacitinib varies between individuals:



- Some patients notice improvement in symptoms within 3 days to 2 weeks
- Many patients see significant improvement by 8 weeks
- Your doctor will typically assess the effectiveness of the induction treatment after 8–16 weeks

If you haven't experienced significant improvement after 16 weeks of treatment, your doctor may consider adjusting your treatment plan

How should Tofacitinib be stored?

- Store at room temperature between 15°C and 30°C
- Keep the tablets in the original container to protect from moisture
- Keep out of reach of children
- Do not use after the expiry date printed on the package

Drug interactions:

Tofacitinib can interact with several medications. It is important to tell your doctor about all medications you are taking, including:



- Other immunosuppressants (e.g., azathioprine, 6-mercaptopurine, methotrexate)
- Medications that affect the CYP3A4 enzyme (e.g., ketoconazole, fluconazole, rifampicin)
- Live vaccines
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Birth control pills
- Blood thinners
- Cholesterol-lowering medications

What monitoring is required while taking Tofacitinib?

Before starting tofacitinib:

- Complete blood count
- Liver function tests
- Kidney function tests
- Lipid profile (cholesterol levels)
- Tuberculosis (TB) screening (skin test, blood test, and/or chest X-ray)
- Hepatitis B and C testing

- Varicella zoster virus (chickenpox) antibody test (if no history of chickenpox or vaccination)
- Pregnancy test for women of childbearing potential

During treatment:

- Regular blood tests to monitor:
 - Complete blood count
 - Liver function
 - Lipid levels (after 4-8 weeks of treatment, then as needed)
- Regular monitoring of symptoms and disease activity
- Periodic skin examinations to check for skin cancer
- Blood pressure monitoring

What are the common side effects of Tofacitinib?

Common side effects (affecting more than 1 in 10 people):

- Upper respiratory tract infections (common cold, sinusitis)
- Headache
- Diarrhoea
- Nasopharyngitis (inflammation of the nose and throat)
- High blood pressure
- Increased cholesterol levels

Less common side effects (affecting between 1 in 100 and 1 in 10 people):

- Herpes zoster (shingles)
- Pneumonia
- Urinary tract infection
- Bronchitis
- Flu
- Sinusitis
- Cystitis
- Sore throat
- Anaemia
- Nausea
- Stomach pain
- Vomiting
- Joint pain
- Swelling of hands, feet, or legs
- Rash
- Fatigue
- Fever

What are the risks associated with Tofacitinib?

Serious risks:

1. **Serious infections:**

- Tofacitinib can reduce your ability to fight infections. This includes:
 - Upper respiratory tract infections
 - Pneumonia
 - Cellulitis (skin infection)
 - Herpes zoster (shingles)
 - Serious infections that may require hospitalisation

2. **Blood clots:**

- Increased risk of blood clots in the veins (deep vein thrombosis or DVT) or lungs (pulmonary embolism)
- The risk is higher in patients taking the 10mg twice daily dose
- The risk is also higher in patients with risk factors such as older age, obesity, a history of blood clots, or who are taking hormonal contraceptives

3. **Cancer risk:**

- Increased risk of certain cancers, particularly lymphomas and non-melanoma skin cancers
- The risk may be higher in current or past smokers
- The risk increases with higher doses and longer duration of treatment
- Regular skin checks are recommended

4. **Gastrointestinal perforations:**

- Rare cases of holes in the wall of the stomach or intestines have been reported
- The risk is higher if you are also taking non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids

5. **Changes in laboratory test results:**

- Decreased white blood cell count
- Decreased red blood cell count (anaemia)
- Increased liver enzymes
- Increased cholesterol levels

6. **Reactivation of herpes zoster (shingles):**

- Tofacitinib significantly increases the risk of developing shingles
- The risk is higher with the 10mg twice daily dose
- Consider vaccination against shingles before starting treatment

7. **Cardiovascular risk:**

- An increased risk of major adverse cardiovascular events (heart attack, stroke) has been observed
- The risk is higher in patients who are 50 years or older with at least one cardiovascular risk factor



Vaccinations and Tofacitinib

Before starting tofacitinib:

It is strongly recommended to update all vaccinations according to the Australian Immunisation Schedule before starting treatment. This includes:

- Influenza vaccine (yearly flu shot)

- Pneumococcal vaccine
- Shingles vaccine (Shingrix is strongly recommended for adults 50 years and older)
- Hepatitis B vaccine (if you are not immune)
- COVID-19 vaccination as per current guidelines

All vaccinations should ideally be completed at least 2-4 weeks before starting tofacitinib.

During tofacitinib treatment:

- **Live vaccines** should be avoided, including:
 - Measles, mumps, rubella (MMR)
 - Varicella (chickenpox)
 - Zoster (Zostavax - but not Shingrix)
 - Oral typhoid
 - Yellow fever
 - BCG (tuberculosis)
 - Oral polio vaccine
- **Non-live vaccines** are generally considered safe but may be less effective while on tofacitinib:
 - Influenza vaccine (yearly)
 - Pneumococcal vaccine
 - Tetanus booster
 - COVID-19 vaccines
 - Shingrix (non-live shingles vaccine)

Always discuss vaccination plans with your gastroenterologist before receiving any vaccine.

Tofacitinib and Pregnancy

Planning pregnancy:

Tofacitinib must not be used during pregnancy.



- Animal studies have shown that tofacitinib may harm the developing foetus
- Women of childbearing potential should use effective contraception during treatment and for at least 4 weeks after the last dose
- Pregnancy testing is recommended before starting treatment

If pregnancy occurs:

- If you become pregnant while taking tofacitinib, inform your doctor immediately
- Your doctor will likely recommend stopping tofacitinib
- You may be enrolled in a pregnancy registry to monitor outcomes

Breastfeeding:



- Tofacitinib should not be used during breastfeeding
- It is not known whether tofacitinib passes into breast milk
- A decision must be made whether to discontinue breastfeeding or to discontinue tofacitinib

Fertility:

- Women may experience temporary infertility while taking tofacitinib
- Fertility should return to normal after stopping the medication
- Discuss with your doctor if you have concerns about fertility

Special Precautions

Increased risk in certain populations:

The risk of side effects may be higher if you:

- Are 65 years of age or older
- Have a history of heart disease or stroke
- Are a current or past smoker
- Have diabetes
- Have high blood pressure
- Have high cholesterol
- Have a history of blood clots
- Have had a lung condition

Surgery:

If you are planning to have surgery, inform your surgeon that you are taking tofacitinib. Your doctor may recommend temporarily stopping tofacitinib before and after surgery to reduce the risk of infection and blood clots.

Travel:

- Consider carrying a letter from your doctor explaining your need for tofacitinib when travelling
- If travelling overseas, check if you need additional vaccinations and discuss with your doctor (as some travel vaccines are live vaccines)
- Ensure you have enough medication for your entire trip, plus extra in case of delays
- Be alert to symptoms of blood clots during long journeys (pain or swelling in the leg, chest pain, shortness of breath)

Skin protection:

Due to the increased risk of skin cancers, it is important to practise sun safety:

- Use sunscreen (SPF 30+ or higher)

- Wear protective clothing
- Seek shade when possible
- Have regular skin checks with your doctor

Where can I find more information?



- Speak to your gastroenterologist, IBD nurse, or pharmacist
- Contact the Gastroenterological Society of Australia (GESA): www.gesa.org.au
- Contact Crohn's & Colitis Australia: www.crohnsandcolitis.com.au or 1800 138 029
- Call Medicines Line: 1300 MEDICINE (1300 633 424)

This information leaflet is not intended to replace medical advice. Always consult your healthcare team with specific questions about your treatment.

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