

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking XELJANZ?

XELJANZ contains the active ingredient tofacitinib. XELJANZ is used to treat rheumatoid arthritis, psoriatic arthritis and ulcerative colitis in adults. For more information, see Section [1. Why am I taking XELJANZ?](#) in the full CMI.

2. What should I know before I take XELJANZ?

Do not take XELJANZ if you have ever had an allergic reaction to tofacitinib or any of the ingredients listed at the end of the CMI.

Do not take XELJANZ if you are already using a biological medicine or a medicine that strongly suppresses the immune system such as azathioprine, 6-mercaptopurine, tacrolimus and ciclosporin, or if you have severe liver problems.

Talk to your doctor if you have any other medical conditions, take any other medicines, plan to have surgery, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take XELJANZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XELJANZ and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take XELJANZ?

- The usual dose for **rheumatoid arthritis** and **psoriatic arthritis** is one 5 mg tablet taken twice a day.
- The usual dose for **ulcerative colitis** is one 10 mg tablet taken twice a day for 8 weeks (induction dose), followed by one 5 mg tablet taken twice a day (maintenance dose). More instructions can be found in Section [4. How do I take XELJANZ?](#) in the full CMI.

5. What should I know while taking XELJANZ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are taking XELJANZ.• Keep all of your appointments, including any blood tests.• Tell your doctor if you have any signs of an infection, or swelling of the leg or arm, leg pain or tenderness, shortness of breath or difficulty breathing, or chest pain.• Tell your doctor if you become pregnant. Use effective birth control while taking XELJANZ.
Things you should not do	<ul style="list-style-type: none">• Do not take XELJANZ to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you. <p>Do not stop taking your medicine, or change the dosage, without checking with your doctor.</p>
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how XELJANZ affects you•
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Store XELJANZ below 30°C.

For more information, see Section [5. What should I know while taking XELJANZ?](#) in the full CMI.

6. Are there any side effects?

Common side effects include a cold, sore throat, runny or blocked nose, pain in your sinus, cough, the flu, cold sore blisters, stomach pain, indigestion, heart burn, nausea, vomiting, diarrhoea, constipation, headaches, dizziness, skin redness or itching, joint or back pain, swollen feet or hands, weight gain. Serious side effects include increased risk of death, blood clots, serious infections (e.g. pneumonia, shingles, tuberculosis), heart attack, skin and lung cancer, blood disorder, gastrointestinal disorder.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

XELJANZ®

Active ingredient(s): *tofacitinib (as citrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XELJANZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XELJANZ.**

Where to find information in this leaflet:

- [1. Why am I taking XELJANZ?](#)
- [2. What should I know before I take XELJANZ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take XELJANZ?](#)
- [5. What should I know while taking XELJANZ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking XELJANZ?

XELJANZ contains the active ingredient tofacitinib.

Tofacitinib belongs to a group of medicines called Janus Kinase (JAK) inhibitors. It works by reducing the activity of the enzyme Janus Kinase, which helps to reduce inflammation.

XELJANZ is used to treat the following inflammatory diseases in adults:

- moderate to severe active rheumatoid arthritis, a long-term disease that mainly causes pain and swelling of your joints.

XELJANZ may be used alone or in combination with other oral medicines (such as methotrexate) when used to treat rheumatoid arthritis.

- active psoriatic arthritis, an inflammatory disease of the joints that is often accompanied by psoriasis. XELJANZ should be used in combination with other oral medicines (such as methotrexate) when used to treat psoriatic arthritis.
- moderate to severe active ulcerative colitis, an inflammatory disease of the large bowel.

If you have ulcerative colitis, you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, your doctor may give you XELJANZ to reduce the signs and symptoms of your disease.

XELJANZ may be used together with other medicines, such as corticosteroids and aminosaliclates, to treat ulcerative colitis. Your doctor will tell you which of these other medicines you should use.

Your doctor may have prescribed XELJANZ for another reason. Ask your doctor if you have any questions about why XELJANZ has been prescribed for you.

2. What should I know before I take XELJANZ?

Warnings

Do not take XELJANZ if:

1. you are allergic to tofacitinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
2. you are already using a biological (injectable) medicine.
3. you are taking other medicines used to strongly suppress your immune system e.g. azathioprine, 6-mercaptopurine, tacrolimus and cyclosporin
4. you have severe liver problems.
5. the expiry date printed on the pack has passed.
6. the packaging is torn or shows signs of tampering.

Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have or have had any of the following medical conditions:
 - blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past
 - an infection, including localised infection (e.g. a leg ulcer)
 - you are being treated for an infection, get a lot of infections or have infections that keep coming back
 - diabetes, HIV/AIDS, a weak immune system or chronic lung disease. People with these conditions have a higher chance of developing infections.
 - hepatitis B or hepatitis C, viruses that affect the liver
 - shingles
 - tuberculosis or have been in close contact with someone with tuberculosis
 - a fungal infection
 - any type of cancer, including skin cancer or a family history of skin cancer
 - diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines
 - liver or kidney problems, including kidney transplant surgery
 - high blood pressure
 - chest pain or any heart problems
 - lung disease or shortness of breath
 - high cholesterol
 - history of allergies or allergic reactions
 - bone-related conditions
 - any other medical conditions.
- take any medicines for any other condition
- plan to have surgery or a medical procedure
- are a smoker or have been a smoker in the past

Your doctor will do blood tests before you start treatment with XELJANZ and while you are taking it. Depending on the results of your blood tests your doctor may suspend or discontinue treatment or prescribe you additional medicines.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

People taking the higher dose (10 mg twice a day) of XELJANZ may have a higher risk of certain side effects, including serious infections, shingles, lung cancers, skin cancers other than melanoma, increased risk of death and blood clots.

Mortality

An increased risk of death has been seen in patients with rheumatoid arthritis who are 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, and taking a higher than recommended dose of XELJANZ. The recommended dose in patients with rheumatoid arthritis and psoriatic arthritis is XELJANZ 5 mg twice a day.

Blood clots

Blood clots in the lungs (pulmonary embolism, PE), veins of the legs or arms (deep vein thrombosis, DVT) and arteries (arterial thrombosis) have happened more often in patients with rheumatoid arthritis who are 50 years of age and older and with at least 1 additional heart disease (cardiovascular) risk factor taking a higher than recommended dose of XELJANZ, especially in obese patients (body mass index [BMI] greater than or equal to 30). The recommended dose in patients with rheumatoid arthritis and psoriatic arthritis is XELJANZ 5 mg twice a day. Blood clots in the lungs have also happened in patients with ulcerative colitis. Some people have died from these blood clots.

Stop taking XELJANZ and tell your doctor right away if you develop signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm.

Serious infections

It is important to tell your doctor if you get symptoms of an infection.

XELJANZ can lower the ability of your immune system to fight infections. Some people have serious infections while taking XELJANZ, including tuberculosis and infections caused by bacteria, fungi or viruses that can spread in your body. In rare cases these infections can be life threatening.

People taking the higher dose (10 mg twice a day) of XELJANZ have a higher risk of serious infections and shingles.

Symptoms of an infection include fever, sweating or chills; muscle aches; cough, shortness of breath, weight loss; warm, red or painful skin or sores on your body; diarrhoea or stomach pain; burning when you urinate or urinating more often than normal, feeling very tired.

Symptoms of tuberculosis include persistent cough, coughing up blood, weight loss, fever and lack of energy.

Your doctor will check for signs and symptoms of tuberculosis before you start treatment. This will include a thorough medical history, a chest X-ray and other tests. Your doctor will also monitor you for signs of tuberculosis while you are being treated with XELJANZ.

Tell your doctor if you have lived in or travelled to countries where there is an increased chance of getting tuberculosis or fungal infections.

Shingles (herpes zoster virus)

Tell your doctor if you have ever had shingles. XELJANZ can reactivate the herpes zoster virus in people who carry this virus.

Serious heart-related problems

In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking XELJANZ had an increased risk of non-fatal heart attacks compared to another type of medicine called tumour necrosis factor (TNF) inhibitors. Serious heart-related problems were more common in older patients and in patients who were current or past smokers.

Cancers

In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking XELJANZ had an increased risk of getting cancers compared to another type of medicine called tumour necrosis factor (TNF) inhibitors. Cancers were more common in older patients and in patients who were current or past smokers.

Asian patients

Tell your doctor if you have Japanese or Korean ancestry. The risk of shingles may be higher in people with Japanese or Korean ancestry.

Hepatitis B virus (HBV) or hepatitis C virus (HCV)

Tell your doctor if you are a carrier of the hepatitis B virus (HBV) or hepatitis C virus (HCV), or if you have hepatitis B or C infection. If you have HBV or HCV in your blood, it may become active while you are taking XELJANZ. This effect has been reported with medicines used to treat rheumatoid arthritis, psoriatic arthritis and ulcerative colitis, including XELJANZ.

Vaccination

Make sure you are up to date with all vaccinations before starting XELJANZ.

Tell your doctor if you have recently been vaccinated or are scheduled for any vaccines. Some vaccines should not be given while you are taking XELJANZ. Check with your doctor before you receive any vaccines. Your doctor will decide whether you need to have herpes zoster vaccination.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. Do not take XELJANZ if you are pregnant or attempting to become pregnant. Your doctor can discuss with you the risks and benefits involved.

Use effective birth control during treatment with XELJANZ and after the last dose, for as long as your doctor recommends, if you are a woman of childbearing age.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if XELJANZ is found in breast milk. Do not breast-feed if you are taking XELJANZ.

Use in children

- The safety and effectiveness of XELJANZ in children and adolescents have not been established.

Use in the elderly

- Patients over 65 years old have an increased chance of getting certain side effects including infections and blood clots.
- In a study in patients with rheumatoid arthritis who were 50 years of age and older with at least 1 additional heart disease (cardiovascular) risk factor, patients taking XELJANZ had an increased risk of getting certain side effects, including heart attacks and cancer. These side effects were more common in older patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with XELJANZ and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- antibiotics to treat bacterial infections such as rifampicin
- medicines to treat fungal infections, such as fluconazole and ketoconazole
- medicines to treat heart rhythm, angina and blood pressure
- medicines to suppress your immune system, such as azathioprine, tacrolimus, ciclosporin and mycophenolate
- any other medicines to treat rheumatoid arthritis, psoriatic arthritis or ulcerative colitis.

XELJANZ must not be taken with some medicines to treat rheumatoid arthritis or psoriatic arthritis such as certolizumab or adalimumab, but can be taken with medicines such as methotrexate, leflunomide and sulfasalazine.

XELJANZ may be used in combination with methotrexate or sometimes alone when used to treat rheumatoid arthritis. In general, fewer side effects were seen when XELJANZ was used alone in rheumatoid arthritis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XELJANZ.

4. How do I take XELJANZ?

How much to take

Your doctor will tell you how many tablets you need to take each day.

Rheumatoid arthritis and Psoriatic arthritis

- The usual dose for rheumatoid arthritis and psoriatic arthritis is one 5 mg tablet taken twice a day
- Your doctor may adjust the dose. This may depend on your medical conditions (e.g. liver or kidney problems),

results of your blood tests and whether you are taking any other medicines.

Ulcerative colitis

- The usual dose for ulcerative colitis is one 10 mg tablet taken twice a day for 8 weeks (induction dose), followed by one 5 mg tablet taken twice a day (maintenance dose).
- Your doctor may adjust the dose depending on your progress, your medical conditions (e.g. liver or kidney problems), results of your blood tests and whether you are taking any other medicines.
- Your doctor may decide to extend the initial 10 mg twice a day treatment by an additional 8 weeks (16 weeks in total), followed by 5 mg twice a day.
- Your doctor may decide to stop XELJANZ if it does not work for you within 16 weeks.
- For patients who have previously taken biological medicines to treat ulcerative colitis (such as those that block the activity of tumour necrosis factor in the body) and these medicines did not work, your doctor will discuss your XELJANZ dose with you.
- If maintaining XELJANZ 5 mg twice a day does not work for you, your doctor may decide to increase the dose to 10 mg twice a day.
- If your treatment is interrupted, your doctor may decide to restart your treatment.

When to take XELJANZ

- Take XELJANZ tablets at about the same time each morning and evening. It will help you remember when to take it.

How to take XELJANZ

- Swallow the tablets whole with a full glass of water.
- You can take XELJANZ with or without food.

How long to take XELJANZ

- Continue taking your medicine for as long as your doctor tells you.
- This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take XELJANZ

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you take too much XELJANZ

If you think that you have taken too much XELJANZ, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking XELJANZ?

Things you should do

- keep all your appointments so that your progress can be checked.
- keep your appointments for blood tests to make sure XELJANZ is working and to check for any side effects.
- wear sunscreen and a hat when outdoors and avoid getting sunburnt.
- get regular skin checks.
- if you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking XELJANZ.
- remind any doctor or dentist you visit that you are taking XELJANZ.
- if you are going to have surgery, tell the surgeon or anaesthetist that you are taking XELJANZ.
- use effective birth control while taking XELJANZ and after the last dose, for as long as your doctor recommends, if you are a woman of childbearing age.

Call your doctor straight away if you:

- have any signs and symptoms of an infection, during or after treatment, such as fever, sweating and chills, burning when you urinate, shortness of breath, cough, phlegm, wounds or warm, red or painful skin or sores on your body, feeling very tired.
XELJANZ may reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection.
- develop a persistent cough, blood in your phlegm or mucous, chest pain, fever, night sweats, weight loss, loss of appetite.
- have any signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, excessive sweating, rapid or irregular heartbeat, swelling of the leg or arm, leg pain or tenderness, or redness or discolouration in the leg or arm.
- notice any new spots on your skin, a spot that looks different, a sore that doesn't heal, a mole or freckle that has changed size, shape, colour or bleeds.
- become pregnant while taking XELJANZ.

Things you should not do

- do not take XELJANZ to treat any other complaints unless your doctor tells you to.
- do not give your medicine to anyone else, even if they have the same condition as you.
- do not stop taking your medicine, or change the dosage, without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XELJANZ affects you.

Drinking alcohol

No information is available.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Store XELJANZ below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<p>Body as a whole:</p> <ul style="list-style-type: none"> • weight gain <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • stomach pain, indigestion or heart burn • nausea (feeling sick), vomiting, diarrhoea or constipation <p>General disorders:</p> <ul style="list-style-type: none"> • swollen feet or hands <p>Infection related:</p> <ul style="list-style-type: none"> • a cold, sore throat, runny or blocked nose, pain in your sinus • cough • the flu • cold sore blisters <p>Muscle or Bone related:</p> <ul style="list-style-type: none"> • joint or back pain <p>Nervous system:</p> <ul style="list-style-type: none"> • headaches, dizziness <p>Skin related:</p> <ul style="list-style-type: none"> • skin, redness or itching 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Signs of a possible serious infection:</p> <ul style="list-style-type: none"> • fever, sweating and chills • burning when you urinate • shortness of breath, cough, phlegm • wounds or warm, red or painful skin or sores on your body 	<p>Call your doctor straight away if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> feeling very tired <p>Lung or heart related:</p> <ul style="list-style-type: none"> persistent cough, coughing up blood, weight loss, lack of energy breathlessness during exercise or a dry cough <p>Liver related:</p> <ul style="list-style-type: none"> fatigue, yellowing of the skin or eyes, dark urine, loss of appetite <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> a stomach ache or pain that won't go away, a change in bowel habits <p>Blood disorders:</p> <ul style="list-style-type: none"> tiredness, headaches, shortness of breath when exercising, dizziness, and looking pale <p>Skin related:</p> <ul style="list-style-type: none"> painful skin rash with blisters a change in the appearance of a freckle, mole or spot, a sore that doesn't heal 	
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body severe rash, itching or hives <p>Signs of a blood clot:</p> <ul style="list-style-type: none"> sudden shortness of breath or difficulty breathing, chest pain, excessive sweating, rapid or irregular heartbeat swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm <p>Blood disorders:</p> <ul style="list-style-type: none"> persistent fever, bruising, bleeding, paleness swelling of the glands in your neck, armpits or groin 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Serious side effects (continued)

Serious side effects	What to do
<p>Signs of meningitis:</p> <ul style="list-style-type: none"> fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light <p>Signs of sepsis:</p> <ul style="list-style-type: none"> fever, chills, uncontrollable shaking, rapid breathing and heart rate, headache, confusion or anxiety, drowsiness, reduced urine <p>Signs of heart attack:</p> <ul style="list-style-type: none"> chest pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> pressure or tightness in the chest and arms that may spread to the jaw, neck or back dizziness, nausea or vomiting 	

If you are over 65 years of age or have diabetes, you have an increased chance of getting certain side effects including infections. This may also be the case if you have chronic lung disease.

Asian patients may have an increased risk of getting certain side effects such as shingles or lung problems.

People with rheumatoid arthritis or problems with their immune system may be at increased risk of cancer, including lymphoma (symptoms include swelling of the glands in the neck, armpit or groin) and lung cancer.

As with some other treatments for rheumatoid arthritis, psoriatic arthritis and ulcerative colitis, XELJANZ may increase the risk of skin cancer.

People taking the higher dose (10 mg twice a day) of XELJANZ may have a higher risk of certain side effects, including serious infections, shingles, lung cancers, skin cancers other than melanoma, increased risk of death and blood clots.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Some side effects (for example, changes in cholesterol level or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What XELJANZ contains

Active ingredient (main ingredient)	tofacitinib
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose croscarmellose sodium magnesium stearate hypromellose titanium dioxide macrogol 3350 triacetin

indigo carmine aluminium lake (present in the 10 mg tablet)
brilliant blue FCF aluminium lake (present in the 10 mg tablet)

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain sucrose.

What XELJANZ looks like

XELJANZ 5 mg is a white, round, film-coated tablet with "Pfizer" on one side and "JKI 5" on the other side. They are available in blister packs of 14 and 56 tablets (AUST R 196987).

XELJANZ 10 mg is a blue, round, film-coated tablet with "Pfizer" on one side and "JKI 10" on the other side. They are available in blister packs of 14 and 56 tablets (AUST R 298307).

Who distributes XELJANZ

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizer.com.au

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This leaflet was prepared in October 2021.