

▼ 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®

tofacitinib (as citrate) tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XELJANZ.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking XELJANZ against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What XELJANZ is used for

XELJANZ is a medicine that is used to treat the following inflammatory diseases in adult patients:

- rheumatoid arthritis
- psoriatic arthritis
- ulcerative colitis

XELJANZ contains the active ingredient tofacitinib. Tofacitinib belongs to a group of medicines called Janus Kinase (JAK) inhibitors. This medicine blocks the activation of parts of your immune system involved in rheumatoid arthritis, psoriatic arthritis and ulcerative

colitis. XELJANZ works by helping to reduce inflammation.

Rheumatoid arthritis

XELJANZ is used to treat adult patients with 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.

Psoriatic arthritis

XELJANZ is used to treat adult patients with 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.

Ulcerative colitis

Ulcerative colitis is 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 aminosalicylates, to treat ulcerative colitis. Your doctor will tell you which of these other medicines you should use.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available on a prescription from your specialist doctor.

The safety and effectiveness of this medicine in children and adolescents have not been established.

Before you take XELJANZ

When you must not take it

Do not take XELJANZ if you have an allergy to:

- the active ingredient, tofacitinib
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives

Do not take XELJANZ if you have severe liver problems.

Do not take XELJANZ if you are already using injectable medicines that depress the immune system, including biologic medicines that block chemical messengers in the

blood which cause inflammation, or medicines used to strongly suppress your immune system including azathioprine, 6-mercaptopurine, tacrolimus and cyclosporin.

Taking XELJANZ with these medicines may increase your risk of infection.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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, skin cancers other than melanoma, increased risk of death and blood clots.

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 heart disease (cardiovascular) risk factor, and who are obese (body mass index [BMI] greater than or equal to 30) 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 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 heart disease (cardiovascular) risk factor 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 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 discolouration in the leg or arm.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you 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
- any other medical conditions.

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.

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.

Tell your doctor if you have had shingles (herpes zoster virus).

XELJANZ can reactivate the herpes zoster virus in people who carry this virus.

Tell your doctor if you have Japanese or Korean ancestry.

The risk of shingles may be higher in people with Japanese or Korean ancestry.

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.

HBV or HCV may become active while you are taking XELJANZ in people who carry the virus in their blood. This has been reported with medicines used to treat rheumatoid arthritis, psoriatic arthritis and ulcerative colitis, including XELJANZ.

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.

Tell your doctor if you plan to have surgery or a medical procedure.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

XELJANZ should not be taken 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.

It is not known if XELJANZ is found in breast milk. Do not breast-feed if you are taking XELJANZ.

If you have not told your doctor about any of the above, tell him/her before you start taking XELJANZ.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by XELJANZ or may affect how well 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, cyclosporin 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take XELJANZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

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

Rheumatoid arthritis and Psoriatic arthritis

The recommended dose is one 5 mg tablet taken twice a day.

Your doctor may adjust the dose. This may depend on your medical conditions (such as decreased liver or kidney function), results of your blood tests and whether or not you are taking any other medicines.

Ulcerative colitis

The recommended dose is one 10 mg tablet taken twice a day for 8 weeks, followed by one 5 mg tablet taken twice a day.

Your doctor may adjust the dose depending on your progress, your medical conditions (such as decreased liver or kidney function), results of your blood tests and whether or not 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 biologic 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 did 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.

How to take it

Swallow the tablets whole with a full glass of water.

You can take XELJANZ with or without food.

When to take it

Take your medicine at about the same time each morning and evening.

It will help you remember when to take it.

How long to take it

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 it

If it is close to 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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much XELJANZ.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using XELJANZ

Things you must do

Tell your doctor immediately if you have any symptoms of tuberculosis or any other infection, during or after treatment.

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.

Tell your doctor if you 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.

Wear sunscreen and a hat when outdoors and avoid getting sunburnt.

Your doctor will conduct regular skin checks for any suspicious spots.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking XELJANZ.

Tell all doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor immediately if you become pregnant while taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests from time to time to make sure XELJANZ is working and to check for side effects.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how XELJANZ affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking XELJANZ.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking XELJANZ, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Emergency Department at your nearest hospital, if you notice any of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe rash, itching or hives
- persistent fever, bruising, bleeding, paleness
- fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light
- 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 discoloration in the leg or arm

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- signs of an infection, 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
- painful skin rash with blisters
- a change in the appearance of a freckle, mole or spot, a sore that doesn't heal
- persistent cough, coughing up blood, weight loss, lack of energy
- a stomach ache or pain that won't go away, a change in bowel habits
- fatigue
- yellowing of the skin or eyes, dark urine, loss of appetite

- breathlessness during exercise or a dry cough
- tiredness, headaches, shortness of breath when exercising, dizziness, and looking pale

The above list includes serious side effects that may require urgent medical attention.

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

- a cold, sore throat, runny or blocked nose, pain in your sinus
- headaches, dizziness
- cough
- stomach pain, indigestion or heart burn
- nausea (feeling sick), vomiting, diarrhoea or constipation
- joint or back pain
- weight gain
- swollen feet or hands
- the flu
- cold sore blisters
- skin, redness or itching.

The above list includes the more common side effects of your medicine.

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.

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

Other side effects not listed above may also occur in some people.

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

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 have a higher risk of skin

cancers. It is not known if XELJANZ increases the risk of other cancers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using XELJANZ

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store XELJANZ or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

XELJANZ 5 mg is a white, round, film-coated tablet with "Pfizer" on one side and "JKI 5" on the other side.

XELJANZ 10 mg is a blue, round, film-coated tablet with "Pfizer" on one side and "JKI 10" on the other side.

XELJANZ film-coated tablets are available in the following pack sizes:

- blister packs of 14 and 56 tablets

Ingredients

XELJANZ contains 5 mg or 10 mg of tofacitinib as the active ingredient.

It also contains:

- 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).

This medicine does not contain sucrose.

Supplier

XELJANZ is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizer.com.au

Australian registration numbers

5 mg tablets (blister pack): AUST R 196987

10 mg tablets (blister pack): AUST R 298307

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