

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **XELJANZ**[®]

Tofacitinib tablets

Pr **XELJANZ**[®] XR

Tofacitinib extended-release tablets

Read this carefully before you start taking **XELJANZ/XELJANZ XR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XELJANZ/XELJANZ XR**.

Serious Warnings and Precautions

Serious Infections

- You should NOT take XELJANZ/XELJANZ XR if you have an active infection.
- XELJANZ/XELJANZ XR is a medicine that affects your immune system. It can lower the ability of your body to fight infections such as tuberculosis, shingles (herpes zoster) and infections caused by other bacteria, fungi, or viruses that can spread throughout the body.
- In some cases, these infections may lead to hospitalization or death.
- Most patients who developed infections were taking other medicines, such as methotrexate or corticosteroids at the same time. These medicines make it harder to fight infections.
- Your healthcare professional will closely monitor you for the signs and symptoms of infections during and after the treatment with XELJANZ/XELJANZ XR.
- Contact your healthcare professional if you have any signs or symptoms of an infection, such as:
 - fever, sweating, or chills,
 - muscle aches,
 - cough, shortness of breath,
 - blood in spit,
 - weight loss,
 - warm, red, or painful skin or sores on your body,
 - diarrhea or stomach pain,
 - burning when you urinate or urinating more often than normal,
 - feeling very tired.
- If a serious infection develops, stop taking XELJANZ/XELJANZ XR and contact your healthcare professional right away.

Cancers and immune conditions

- Lymphoma, lung cancer, and other cancers have been reported in patients treated with XELJANZ.
- Your healthcare professional will closely monitor you for signs and symptoms of cancer and other serious conditions during treatment with XELJANZ.

Blood clots

- Blood clots in the veins of your legs or arms (deep vein thrombosis, DVT), arteries (arterial thrombosis) or lungs (pulmonary embolism, PE) can happen in some people taking XELJANZ. This may be life-threatening and cause death.
- Stop taking XELJANZ/XELJANZ XR and seek medical help right away if you develop any signs or symptoms of:
 - Blood clots in your leg (such as swelling, pain or tenderness); or
 - Blood clots in your lung (such as sudden unexplained chest pain or shortness of breath).

Major heart problems

- Major heart problems have been reported in Rheumatoid Arthritis patients treated with XELJANZ/XELJANZ XR.
- Talk to your healthcare professional about possible heart disease risk factors before you start taking XELJANZ/XELJANZ XR.
- If you develop signs and symptoms of a heart problem, stop taking XELJANZ/XELJANZ XR and contact your healthcare professional right away. Symptoms may include:
 - new or worsening chest pain,
 - shortness of breath,
 - irregular heartbeats,
 - swelling of the legs.

What is XELJANZ/XELJANZ XR used for?

XELJANZ/XELJANZ XR:

- **Rheumatoid Arthritis**
XELJANZ/XELJANZ XR (tofacitinib) is used to treat adults with rheumatoid arthritis (RA) when other treatments do not work. XELJANZ/XELJANZ XR may be taken alone or in combination with methotrexate.

XELJANZ:

- **Psoriatic Arthritis**
XELJANZ is used to treat adults with active psoriatic arthritis (PsA) when other medicines do not work. XELJANZ may be taken alone or in combination with methotrexate or other medicines called conventional synthetic disease modifying antirheumatic drugs (csDMARDs).
- **Ankylosing Spondylitis**
XELJANZ (tofacitinib) is used to treat adults with active ankylosing spondylitis (AS) when other medicines do not work or are not appropriate. Ankylosing spondylitis is a disease that primarily causes inflammation in the spine.
- **Active Juvenile Idiopathic Arthritis (JIA)**
XELJANZ is used in children (body weight of 40 kg or higher), when other medicines do not work or are not appropriate, to treat:

- active polyarticular juvenile idiopathic arthritis (pJIA). This is a long-term disease that mainly causes joint pain and swelling.
- juvenile psoriatic arthritis (jPSA). This is a disease that causes joint pain and inflammation along with a skin problem called psoriasis.

XELJANZ may be taken alone or together with methotrexate depending on the patient.

- **Ulcerative Colitis**

XELJANZ is used to treat adults with moderately to severely active ulcerative colitis (UC) when other medicines do not work.

How does XELJANZ/XELJANZ XR work?

XELJANZ/XELJANZ XR is a Janus Kinase (JAK) inhibitor. JAK is a type of enzyme which helps start the immune response in your body. XELJANZ/XELJANZ XR is believed to interfere with the activity of the JAK enzyme to reduce the immune response. This helps reduce signs and symptoms of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

What are the ingredients in XELJANZ/XELJANZ XR?

Medicinal ingredients: Tofacitinib citrate

Non-medicinal ingredients:

XELJANZ:

5 mg tablet core contains: Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose. The film coat contains: HPMC 2910/Hypromellose 6cP, Lactose Monohydrate, Macrogol/PEG3350, Titanium dioxide, Triacetin (Glycerol Triacetate)

10 mg tablet core contains: Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose. The film coat contains: FD&C blue #1/brilliant blue FCF aluminum lake, FD&C blue #2/indigo carmine aluminum lake, HPMC 2910/Hypromellose 6cP, lactose monohydrate, macrogol/PEG3350, titanium dioxide, triacetin (glycerol triacetate)

XELJANZ XR:

Ammonium Hydroxide, Cellulose Acetate, Copovidone, Ferrosoferric Oxide/black iron oxide, HPMC 2910/Hypromellose, Hydroxyethyl Cellulose, Hydroxypropyl Cellulose, Magnesium Stearate, Propylene Glycol, red iron oxide, Shellac Glaze, Sorbitol, Titanium Dioxide, Triacetin

XELJANZ/XELJANZ XR comes in the following dosage forms:

XELJANZ: 5 mg and 10 mg tablets in bottles or foil blisters.

XELJANZ XR: 11 mg tablets in bottles.

Do not use XELJANZ/XELJANZ XR if:

- you are allergic to tofacitinib or any other non-medicinal ingredients in XELJANZ/XELJANZ XR.
- you are pregnant or are planning to become pregnant.

- you are breast-feeding or intend to breast-feed. Talk to your healthcare professional about the best way to feed your baby while taking XELJANZ/XELJANZ XR.
- you have severe liver problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XELJANZ/XELJANZ XR. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection, get a lot of infections or have infections that keep coming back;
- have diabetes, HIV/AIDS, or a weak immune system. People with these conditions have a higher chance for infections;
- have tuberculosis, or a history of tuberculosis or have been in close contact with someone with tuberculosis;
- have or have had hepatitis B or C;
- have known narrowing or blockage of your digestive tract (intestines or another part of your bowel are not as wide as normal). This is important if you will be taking XELJANZ XR or if you are switching from XELJANZ to XELJANZ XR;
- have gastrointestinal problems, including gastrointestinal perforations (tear in the stomach or intestines), diverticulitis (inflammation in parts of the large intestine), ulcers in your stomach or intestines;
- have low blood counts. Treatment with XELJANZ/XELJANZ XR can be associated with low red blood cell counts (anemia), or with low white blood cell counts (neutrophils or lymphocytes);
- have high cholesterol;
- have or have had any type of cancer;
- have liver problems;
- have kidney problems;
- have a history of interstitial lung disease (diseases that inflame or scar lung tissue);
- have muscle pain or muscle weakness;
- develop new skin lesions during or after therapy or if existing lesions change appearance;
- have received any vaccines (shots) within 1 month prior to starting XELJANZ/XELJANZ XR or are planning to get vaccinated. Certain types of vaccines (shots) should not be given when taking XELJANZ/XELJANZ XR. Before you start XELJANZ/XELJANZ XR, you should be up to date with all recommended vaccinations, including a shingles vaccine;
- have had blood clots in your legs (deep vein thrombosis), eyes (retinal venous thrombosis) or lungs (pulmonary embolism) or have been told you are at risk of blood clots;
- have problems with your blood clotting (thrombophilia);
- have chest pain, heart failure or any heart problems, or heart disease risk factors, such as if you:
 - are a current or past smoker,
 - have high blood pressure (hypertension),
 - have diabetes,
 - have a family history of premature coronary heart disease,
 - have had coronary artery disease. This is when blood vessels that supply your heart are clogged;
- have other diseases associated with rheumatoid arthritis, such as: lumps (nodules), anemia, lung problems, a type of immune problem called Sjögren's syndrome;
- are of Asian descent. You may be at increased risk of serious side effects;

- have risk factors for broken bones, such as if you: are older than 65 years of age, are a woman, or take a type of medicine called corticosteroids.

Other warnings you should know about:

Blood tests and monitoring

You may need blood tests before you start XELJANZ/XELJANZ XR. These tests may be repeated while you are taking XELJANZ/XELJANZ XR. Your healthcare professional will also monitor your liver tests and blood cholesterol levels 4 to 8 weeks after you start receiving XELJANZ/XELJANZ XR-and routinely thereafter. These will help your healthcare professional find out how XELJANZ/XELJANZ XR is affecting your blood and how well your liver is working.

Female patients

Pregnancy and birth control

- Avoid becoming pregnant while taking XELJANZ/XELJANZ XR. It may harm your unborn baby.
- If you are of child-bearing age, use an effective method of birth control while taking XELJANZ/XELJANZ XR. Continue using birth control for 4 to 6 weeks after you stop taking XELJANZ/XELJANZ XR.

Adults aged 65 years and older

Side effects, including serious side effects, have occurred more often in patients aged 65 years and older.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XELJANZ/XELJANZ XR:

- other medicines used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Active Juvenile Idiopathic Arthritis, Juvenile psoriatic arthritis or ulcerative colitis, including:
 - Biologics such as: abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab, secukinumab, ustekimumab, vedolizumab,
 - Other JAK inhibitors such as: baricitinib and upadacitinib.
- medicines that affect your immune system (such as azathioprine, 6-mercaptopurine, tacrolimus, sirolimus, cyclosporine)
- antiarrhythmics (medicines used to treat heart rhythm problems)
- beta-blockers (medicines used to slow the heart or lower blood pressure), and calcium channel blockers (medicines used to lower blood pressure)
- cholinesterase inhibitors (medicines used to treat Alzheimer’s)
- HIV protease inhibitors
- a medicine used to treat bacterial infections like tuberculosis called rifampin, and medicines for fungal infections (such as ketoconazole, fluconazole)
- grapefruit juice
- St. John’s Wort (an herbal medicine also known as hypericum perforatum). It may reduce the response to XELJANZ/XELJANZ XR

How to take XELJANZ/XELJANZ XR:

- Always take XELJANZ/XELJANZ XR exactly as your healthcare professional tells you.
- XELJANZ/XELJANZ XR-can be taken with or without food.
- Your doctor may reduce the dose if you have liver or kidney problems. You should not increase the dose.
- XELJANZ/XELJANZ XR-should not be used if you have or develop a serious infection until the infection is controlled.

Your healthcare professional may prescribe XELJANZ/XELJANZ XR alone or in combination with other medication(s). If you receive treatment with another drug, your healthcare professional will tell you how to take it. Be sure to read the package leaflets for the other drugs as well as this one.

Usual dose:

Adults (18 years and older):

XELJANZ:

Rheumatoid Arthritis:

- The recommended dose is 5 mg taken by mouth twice daily.

Psoriatic Arthritis:

- The recommended dose is 5 mg, taken by mouth twice daily.

Ankylosing spondylitis:

- The recommended dose is 5 mg, taken by mouth twice daily.

Ulcerative Colitis:

- The recommended dose is 10 mg, twice daily for the first 8 weeks. After 8 weeks, your doctor will decide to give you 5 mg or 10 mg twice daily for maintenance.
- Your doctor may decide to stop your treatment with XELJANZ if it does not work for you within 16 weeks.

XELJANZ XR:

Rheumatoid Arthritis:

- The recommended dose is 11 mg, taken by mouth once daily.
- Swallow XELJANZ XR tablets whole. Do NOT crush, split or chew the tablets.

Children (body weight of at least 40 kg, less than 18 years old):

XELJANZ:

Active Juvenile Idiopathic Arthritis (JIA):

- Body weight is at least 40 kg: the recommended dose is one 5 mg tablet, taken twice daily.

Overdose:

If you think you, or a person you are caring for, have taken too much XELJANZ/XELJANZ XR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed your dose of XELJANZ/XELJANZ XR, take the next dose as planned at the next scheduled time. Do NOT take a double dose to make up for a forgotten dose.

What are possible side effects from using XELJANZ/XELJANZ XR:

These are not all the possible side effects you may have when taking XELJANZ/XELJANZ XR. If you experience any side effects not listed here, tell your healthcare professional.

The side effects of XELJANZ/XELJANZ XR-include:

- Upper respiratory tract infection (such as a cold)
- Nasopharyngitis (nose or throat infection, runny or stuffy nose), cough
- Headache, dizziness
- Diarrhea, vomiting, nausea (feeling queasy, feeling like you may throw up)
- Indigestion (heartburn or upset stomach)
- Back pain, joint pain
- Rash, acne
- Muscle weakness/pain

If any of the above affects you severely, tell your healthcare professional.

XELJANZ/XELJANZ XR may cause abnormal blood test results, including changes in cholesterol levels, white or red blood cell counts or creatinine levels (a protein that may increase in people with kidney problems). Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Broken bones		✓	
Cellulitis: skin infection with redness, swelling and pain		✓	
Gastritis: stomach ache, loss of appetite		✓	
Herpes Zoster (shingles): skin rash or blisters usually on one side of the body with itching, burning or tingling pain			✓
Hypertension (high blood pressure): measured high blood pressure, sometimes with headache or nosebleed		✓	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			✓
Pneumonia: infection with coughing, fever, fatigue		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Urinary tract infections: difficulty or increased need to urinate; pain or burning sensation when passing urine, pain in the pelvis or mid-back, urine that appears cloudy		✓	
UNCOMMON			
Allergic reaction: hives, rash, swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing			✓
Anemia/neutropenia/ lymphopenia (low blood cell counts): fatigue, loss of energy, weakness, shortness of breath		✓	
Bronchitis: persistent cough, fatigue, shortness of breath		✓	
Congestive heart failure: shortness of breath when you exert yourself or lie down, swelling in your legs, ankles and feet, irregular heartbeat, persistent cough			✓
Deep vein thrombosis (blood clot in the leg): swelling, pain or tenderness in the leg			✓
Retinal venous thrombosis (blood clot in the eyes): blurry vision, partial or complete loss of vision			✓
Flu: cough, sore throat, feverish chills		✓	
Increased creatine kinase levels: muscle weakness and/or muscle pain	✓		
Kidney problems: change in the amount, frequency or colour (pale or dark) of urine		✓	
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, throwing up, loss of appetite with itching			✓
Lung cancer: Worsening cough, shortness of breath, chest pain, loss of appetite, coughing up blood, fatigue, unexplained weight loss			✓
Lymphoma (cancer of the lymphatic system): painless swelling of lymph node, swollen tonsils, fever, chills, night sweats, feeling tired, itching, unexplained weight loss, loss of appetite, persistent coughing/ difficulty breathing or not being able to breathe, and headache			✓
Peripheral edema: swelling of legs and ankles or the arms and hands		✓	
Pulmonary embolism (blood clot in the lung): sharp chest pain, coughing up blood, sudden shortness of breath			✓
Skin cancer: lesions during or after therapy or if existing lesions change appearance		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C.

Keep out of sight and reach of children.

If you want more information about XELJANZ/XELJANZ XR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca/>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised APR 12, 2024