PART III: CONSUMER INFORMATION

PrXELJANZ®
Tofacitinib tablets

Pr XELJANZ® XR
Tofacitinib extended-release tablets

This leaflet is part III of a three-part "Product Monograph" published when XELJANZ/XELJANZ XR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XELJANZ/XELJANZ XR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Rheumatoid Arthritis
XELJANZ/XELJANZ XR (tofacitinib) is used to treat rheumatoid arthritis (RA) when other treatments do not work.

Psoriatic Arthritis
XELJANZ is used to treat active psoriatic arthritis (PsA) when other medicines do not work.

Ulcerative Colitis
XELJANZ is used to treat moderately to severely active ulcerative colitis (UC) when other medicines do not work

What it does:
XELJANZ/XELJANZ XR is believed to interfere with the activity of an enzyme called Janus kinase (JAK), which activates other cellular components which normally start the immune response in your body. By reducing the immune response XELJANZ/XELJANZ XR reduces the signs and symptoms of rheumatoid arthritis and psoriatic arthritis. XELJANZ also reduces the sign and symptoms of ulcerative colitis.

When it should not be used:
- If you are allergic to tofacitinib or any other non-medicinal ingredients in XELJANZ/XELJANZ XR, you should not take XELJANZ/XELJANZ XR (see **What the non-medicinal ingredients are**).
- Do not take this medication if you are pregnant or are planning to become pregnant.
- Do not take this medication if you are breast-feeding or intend to breast-feed. Talk to your doctor about how to feed your child while taking XELJANZ/XELJANZ XR.
- Do not take this medication if you have a severe liver insufficiency.

What the medicinal ingredient is:
The active ingredient of XELJANZ/XELJANZ XR is called tofacitinib citrate

What the non-medicinal ingredients are:
XELJANZ:
The 5 mg tablet core contains: Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose. The film coat contains HPMC 2910/Hypromellose 6 cP, Lactose Monohydrate, Macrogol/PEG 3350, Titanium dioxide, Triacetin (Glycerol Triacetate)

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

XELJANZ XR: ammonium hydroxide, cellulose acetate, copovidone, ferrosoferric oxide/black iron oxide, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/hypromellose, magnesium stearate, propylene glycol, red iron oxide, shellac glaze, sorbitol, titanium dioxide, triacetin.

What dosage forms it comes in:
XELJANZ is supplied as 5 mg and 10 mg tablets and is available in bottles or foil blisters.

XELJANZ XR is supplied as 11 mg tablets and is available in bottles.

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions

- XELJANZ/XELJANZ XR is a medicine that affects your immune system and can lower the ability of your body to fight infections such as tuberculosis, and infections caused by other bacteria, fungi, or viruses that can spread throughout the body. These infections may lead to hospitalization or death. Most patients who developed these infections were taking other medicines that make it harder to fight infections at the same time such as methotrexate or corticosteroids. You should not be using XELJANZ/ XELJANZ XR if you have any kind of infection.
- If a serious infection develops, stop XELJANZ/XELJANZ XR and contact your doctor.
- Your doctor will closely monitor you for the signs and symptoms of infection during and after the treatment with XELJANZ/ XELJANZ XR.
- Lymphoma, other cancers and other serious conditions have been reported in patients treated 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.
- If you develop any signs or symptoms of a blood clot in your leg (such as swelling, pain or tenderness in the leg) or in your lung (such as sudden unexplained chest pain or shortness of breath) stop XELJANZ and seek immediate medical help.

BEFORE or while taking XELJANZ or XELJANZ XR, tell your healthcare professional if you:
- think you have an infection or have 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;
- 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 gastrointestinal perforations (tear in the stomach or intestines);
- have diverticulitis (inflammation in parts of the large intestine);
- have 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). Your healthcare professional will monitor your blood counts regularly after you start XELJANZ/XELJANZ XR, and may adjust your dose of XELJANZ/XELJANZ XR or withhold the drug temporarily in the event your blood counts drops too low, or administer additional supportive medicines to help your body regain normal blood cell levels;
- have high cholesterol. Your healthcare professional should monitor your liver tests and blood cholesterol levels 4-8 weeks after you start receiving XELJANZ/XELJANZ XR and routinely thereafter;
- have or had any type of cancer;
- have liver or kidney problems;
- have a history of interstitial lung disease;
- have muscle pain or muscle weakness;
- develop new skin lesions during or after therapy or if existing lesions change appearance;
- 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 chest pain or any heart problems;
- are over the age of 65 or of Asian descent, you may be at increased risk of serious side effects.
- have had blood clots in your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have been told you are at risk of blood clots. Blood clots in the legs and lungs can happen in some people taking XELJANZ. This may be life-threatening and cause death. If you have any signs or symptoms of blood clots while you are being treated with XELJANZ, including swelling, pain or tenderness in the leg, sudden unexplained chest pain, or shortness of breath, stop XELJANZ and seek immediate medical help.
- have problems with your blood clotting (thrombophilia)
- have chest pain
- have heart failure or any heart problems

BEFORE or while taking XELJANZ XR, tell your doctor if you have known narrowing or blockage of your digestive tract (intestines or another part of your bowel are not as wide as normal).

If you are of child-bearing age, you should use an effective method of birth control while taking XELJANZ/XELJANZ XR and for 4 to 6 weeks after you stop taking XELJANZ/XELJANZ XR.

INTERACTIONS WITH THIS MEDICATION

It is important that your healthcare professional be aware of all medications you are taking prior to starting XELJANZ/XELJANZ XR including biologics such as Cimzia™, Cosentyx®, Enbrel®,Humira®, Kineret®, Orencia®, Remicade®, Rituxan®, Entyvio®, Simponi™ and Stelara®.

- Tell your doctor if you are taking immunosuppressants (e.g. azathioprine, 6-mercaptopurine, tacrolimus, sirolimus, cyclosporine), antiarrythmics, beta-blockers, calcium channel blockers, cholinesterase inhibitors, HIV protease inhibitors, rifampin, ketoconazole, fluconazole.
- Tell your doctor if you have received any vaccines (shots) within 1 month prior to starting XELJANZ /XELJANZ XR.
- Avoid grapefruit juice.
- St. John's Wort (an herbal medicine also known as hypericum perforatum) may reduce the response to XELJANZ/XELJANZ XR.

PROPER USE OF THIS MEDICATION

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.

Usual adult dose:

Rheumatoid Arthritis:

- The recommended dose of XELJANZ is 5 mg taken by mouth twice daily.
- The recommended dose of XELJANZ XR is 11 mg taken by mouth once daily. Swallow XELJANZ XR tablets whole. Do not crush, split or chew the tablets.
- Patients taking XELJANZ/XELJANZ XR are usually also prescribed methotrexate.

Psoriatic Arthritis:

- The recommended dose of XELJANZ is 5 mg taken by mouth twice daily.
- Patients taking XELJANZ are also prescribed methotrexate or another conventional synthetic DMARD (csDMARD).

Ulcerative Colitis:

- The recommended dose of XELJANZ 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 XELJANZ if XELJANZ does not work for you within 16 weeks.
- XELJANZ may be used together with certain other medicines, such as corticosteroids and aminosalicylates to treat ulcerative colitis.

Overdose

In case of a drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

These are not all the possible side effects you may feel when taking XELJANZ/XELJANZ XR. If you experience any side effects not listed here, contact 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)
- Headache
- Diarrhea
- Nausea (feeling queasy, feeling like you may throw up)
- Indigestion (heartburn or upset stomach)
- Cough
- Dizziness
- Vomiting
- Back pain
- Joint pain
- Rash
- Muscle weakness/pain

If any of the above affects you severely, tell your doctor or pharmacist.

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 doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Pneumonia: infection with coughing, fever, fatigue		✓	
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		✓	
High blood pressure		✓	
Gastritis: abdominal pain, loss of appetite		✓	
Shingles/Herpes Zoster: skin rash or blisters usually on one side of the body with itching, burning or tingling pain			✓
Cellulitis: skin infection with redness, swelling and painful skin		✓	
UNCOMMON			

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	**Talk with your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Blood clot in the leg (deep vein thrombosis): swelling, pain or tenderness in the leg			✓
Blood clot in the lung (pulmonary embolism): chest pain, or shortness of breath			✓
Bronchitis: persistent cough, fatigue, shortness of breath		✓	
Flu: cough, sore throat, feverish chills		✓	
Skin cancer: lesions during or after therapy or if existing lesions change appearance		✓	
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			✓
Low blood cell counts (anemia/neutropenia/ lymphopenia): fatigue, loss of energy, weakness, shortness of breath		✓	
Peripheral edema: swelling of legs and ankles or the arms and hands		✓	
Congestive heart failure: shortness of breath when you exert yourself or lie down, swelling in your legs, ankles and feet, irregular heartbeat, persistent cough			✓
Allergic reaction: hives, rash, swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing			✓

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

HOW TO STORE IT

Store between 15°C and 30°C.
Keep out of sight and reach of children.

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.

MORE INFORMATION

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.html), the manufacturer's website (http://www.Pfizer.ca) or by calling the sponsor, Pfizer Canada ULC, at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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