XELJANZ® FILM-COATED TABLETS

Tofacitinib citrate (5 mg)

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What XELJANZ is used for

XELJANZ is used for the treatment of adult patients with moderately to severely active rheumatoid arthritis in whom methotrexate did not work well or have had difficulty handling methotrexate due to its side effects. It may be used as a single agent or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

XELJANZ is also used for the treatment of adult patients with active psoriatic arthritis (PsA) in whom methotrexate or other similar medicines called nonbiologic disease-modifying antirheumatic drugs (DMARDs) did not work well or cannot be tolerated.

XELJANZ is also used for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) in whom tumour necrosis factor (TNF) blockers did not work well or cannot be tolerated.

How XELJANZ works

XELJANZ contains the active substance tofacitinib which block proteins called JAK. It preferentially inhibits JAK1 and JAK3 which prevents the activation and reduce the activity of several inflammatory signals called cytokines. These inflammatory signals are important in the activation, function and multiplication of our body's white blood cells. Hence, blocking these signals will help to control our body's immune responses involved in rheumatoid arthritis and psoriatic arthritis.

By blocking excess inflammation, XELJANZ helps to reduce symptoms such as pain and swelling in your joints and can improve your performance of daily tasks.

Before you use XELJANZ

- *<u>When you must not use it</u>*

Do not take XELJANZ

- If you are allergic to tofacitinib or any of the other ingredients of this medicine
- If you have an active severe infection such as tuberculosis or pneumonia
- If you have severe liver problems, including cirrhosis (scarring of the liver)
- If you are pregnant or breast-feeding

If you are not sure regarding any of the information provided above, please contact your doctor.

Pregnancy and lactation

If you are a woman of childbearing potential, you should use effective birth control during treatment with XELJANZ and for at least 4 weeks after the last dose.
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is not known if XELJANZ will harm an unborn baby. XELJANZ must not be used during pregnancy unless clearly necessary. Tell your doctor right away if you become pregnant while taking XELJANZ.

It is not known if XELJANZ is found in breast milk. If you are taking XELJANZ and breastfeeding, you must stop breast-feeding until you talk to your doctor about stopping treatment with XELJANZ. .

- *<u>Before you start to use it</u>*

Talk to your doctor or pharmacist regarding these before taking XELJANZ

- If you think you have an infection or have **symptoms of an infection** such as fever, sweating, chills, muscle aches, cough, shortness of breath, new phlegm or change in phlegm, weight loss, warm, red or painful skin or sores on your body, difficulty or pain when swallowing, diarrhoea or stomach pain, burning when you urinate or urinating more often than normal, feeling very tired
- if you have **any condition that increases your chance of infection** (e.g., diabetes, HIV/AIDS, or a weak immune system)
- if you have any kind of infection, are being treated for any infection, or if you have infections that keep coming back. Tell your doctor immediately if you feel unwell. XELJANZ can 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.
- If you have or have history of tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting XELJANZ and may retest during treatment.
- If you have any chronic lung disease.
- If you have liver problems
- If you have or had hepatitis B or hepatitis C (viruses that

affect the liver). The virus may become active while you are taking XELJANZ. Your doctor may do blood tests for hepatitis before you start treatment with XELJANZ and while you are taking XELJANZ

- if you are 65 years of age and older, if you ever had any type of cancer previously. and also if you are a current or past smoker. XELJANZ can affect the immune system and may increase your risk of certain cancers. Lymphoma (White blood cell cancer) lung cancerand other cancers (such as breast, skin, prostate and pancreatic) have been reported in patients treated with XELJANZ. If you develop cancer while taking XELJANZ your doctor will review whether to stop XELJANZ treatment.
- if you are at known risk of fractures, e.g., if you are 65 years of age and older, you are a female, or take corticosteroids (e.g., prednisone).
- If you have raised blood pressure, raised cholesterol levels, diabetes; or past smoker these factors need to be monitored while receiving XELJANZ
- Cases of non-melanoma skin cancer have been observed in patients taking XELJANZ. Your doctor may recommend that you have regular skin examinations while taking XELJANZ. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- If you have had an inflammation of the large intestine (diverticulitis) or ulcers in your stomach or intestines
- If you have severe kidney problems
- If you are planning to get vaccinated, tell your doctor. Certain types of vaccines should not be given when taking XELJANZ. Before you start XELJANZ, you should be up to date with all recommended vaccinations. Your doctor will decide whether you need to have herpes zoster vaccination.
- Vaccination with live vaccines should occur at least 2 weeks but preferably 4 weeks prior to initiation of XELJANZ. if you are planning to get vaccinated, tell your doctor. Certain types of vaccines should not be given when taking XELJANZ. Before you start XELJANZ, you should be up to date with all recommended vaccinations. Your doctor will decide whether you need to have herpes zoster vaccination.

There have been reports of patients treated with XELJANZ who have developed blood clots in the lungs or veins. Your doctor will evaluate your risk to develop blood clots in the lungs or veins and determine if XELJANZ is appropriate for you. If you have already had problems on developing blood clots in lungs and veins or have an increased risk for developing this (for example: if you are seriously overweight, if you have cancer, heart problems, diabetes, experienced a heart attack (within previous 3 months), recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives), if you are of older age, or if you smoke currently or in the past, your doctor may decide that XELJANZ is not suitable for you.

Monitoring tests performed before and during treatment with XELJANZ

- Your doctor should perform blood tests before you start taking XELJANZ, and after 4 to 8 weeks of treatment and then every 3 months, to determine if you have a low white blood cell (neutrophil or lymphocyte) count, or a low red blood cell count (anaemia). You should not receive XELJANZ if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your XELJANZ treatment to reduce the risk of infection (white blood cell counts) or anaemia (red blood cell counts).
- Your doctor may also perform other tests, for example to check your blood cholesterol levels or monitor the health of your liver. Your doctor should test your cholesterol levels 8 weeks after you start receiving XELJANZ. Your doctor should perform liver tests periodically.

Taking other medicines

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- Tell your doctor if you have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking XELJANZ.
- Some medicines should not be taken with XELJANZ. If taken with XELJANZ, they could cause an inappropriate level of XELJANZ in your body, and the dose of XELJANZ may require adjustment. You should tell your doctor if you are using medicines (taken by mouth) that contain any of the following active substances:

- antibiotics such as rifampin, used to treat bacterial infections
- fluconazole and ketoconazole used to treat fungal infections.

- XELJANZ is not recommended for use with medicines that depress the immune system, including so called targeted biologic (antibody) therapies, such as those that inhibit tumour necrosis factor, interleukin 17, interleukin 12/interleukin 23, anti-integrins, and strong chemical immunosuppressants including azathioprine, mercaptopurine, ciclosporin, and tacrolimus. Taking XELJANZ with these medicines may increase your risk of side effects including infection.
- Serious infections and fractures may happen more often in people who also take corticosteroids (e.g., prednisone).

How to use XELJANZ

- *How much to use*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 5 mg twice a day for rheumatoid arthritis and psoriatic arthritis. The recommended dose is 10 mg twice a day for 8 weeks for ulcerative colitis but maintenance dose is 5 mg only. Your doctor may reduce the dose if you have liver or kidney problems. If you are undergoing dialysis, dose should be administered after the dialysis session on dialysis days. You should not increase or decrease the dose on your own.

- *When to use it*

XELJANZ is for oral use. Take your medication at the same time every day (one tablet in the morning and one tablet in the evening). You can take XELJANZ with or without food.

- *How long to use it*

Continue taking XELJANZ for as long as your doctor recommends. You should not stop taking XELJANZ without discussing this with your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- *If you forget to use it*

Do not take a double dose to make up for a forgotten tablet. Take your next tablet at the usual time and continue as before.

- *If you use too much (overdose)*

Contact your doctor or pharmacist immediately and go to the Emergency Department of your nearest hospital. You will be monitored for signs and symptoms of adverse reactions.

While you are using XELJANZ

- *Things you must do*

- Take your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant. Tell your doctor if you wish to breastfeed.
- Tell all the doctors and pharmacists treating you that you are taking XELJANZ, or if you will be taking any other medicines.
- Take all your blood tests regularly and on time.
- If you experience allergic reactions such as chest tightness, wheezing, severe dizziness or light headedness, swelling of the lips, tongue or throat, itching or skin rash when taking XELJANZ, or soon after taking XELJANZ, tell your doctor immediately.
- If you have any kind of infection or if you have any symptoms of an infection (as described above) tell your doctor immediately, especially if you are aged 65 years and above, have diabetes and are taking medicines that can reduce your immunity such as corticosteroids.
- If you experience weakness in your muscles, worsening shortness of breath or develop yellow skin, nausea or vomiting, tell your doctor immediately.
- If you experience thrombosis/deep vein thrombosis (blood clot in a blood vessel i.e. veins or arteries) characterized by cramps and pain in legs or other parts of the body, or pulmonary embolism which is a blockage of an artery in the lungs by a substance that has moved from elsewhere in the body through the bloodstream, visit your doctor immediately. Your doctor may stop the medicine.
- If you develop any symptoms of ulcers in your stomach or intestines or symptoms of inflammation of the large intestine (diverticulitis) such as fever, abdominal pain, blood in the stool and unexplained changes in bowel habits, tell your doctor. It is rare for people taking XELJANZ to get holes in their stomach or intestine, however this happens most often in people who had a history of diverticulitis and in people who take non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids or methotrexate.
- If you develop any type of cancer, tell your doctor.
- Talk to your doctor if you do not feel better or if you feel worse when taking

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XELJANZ.
- If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- Keep this leaflet. You may need to read it again. If you have further questions, ask your doctor or pharmacist.

- *Things you must not do*

- Do not stop taking XELJANZ unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their signs of illness are the same as yours. It may harm them.

Talk to your doctor straight away:
- if you develop sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm while taking XELJANZ, as these may be signs of a clot in the lungs or veins.
- If you experience acute changes to your eyesight (blurry vision, partial or complete loss of vision), as this may be a sign of blood clots in the eyes.
- If you, your partner or your caregiver notice new onset of severe headaches, which can be accompanied by nausea and vomiting, fainting, dizziness or light headedness, temporary vision problems, weakness on one side of the body, progressive decline in mental status, seizures, or loss of consciousness, as these may be a sign of blood clots in veins around the brain.
- If you develop signs and symptoms of a heart attack including severe chest pain or tightness (that may spread to arms, jaw, neck, back), shortness of breath, cold sweat, light headedness or sudden dizziness. There have been reports of patients treated with XELJANZ who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if XELJANZ is appropriate for you.
- If you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

- *Things to be careful of*

Driving and using machines

XELJANZ has no or limited effect on your ability to drive or use machines..

Side Effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common infections are:
- pneumonia and bronchitis (lung infection)
- cellulitis (bacterial skin infection)
- shingles (herpes zoster a type of viral infection)
- upper respiratory tract infections
- nasopharyngitis
- urinary tract infections
-Acne

Other side effects which have been observed with XELJANZ are listed below:
Diarrhoea, headache, high blood pressure (hypertension), low red blood cell count (anaemia), inflammation of the large intestine (diverticulitis), dehydration, poor sleep, abnormal sensation of skin (paraesthesia), shortness of breath or difficulty breathing, cough, sinus congestion stomach (belly) pain (which may be from inflammation of the stomach lining), vomiting, nausea, indigestion, fat accumulate in liver cells, rash, redness and itching of skin, joint pain, tendon inflammation, joint swelling, pain in the muscles, fever, fatigue (tiredness), swelling of the feet and hands.
Cancer of lungs, breast, gastric, colorectal, renal cell, prostate, lymphatic system, melanocytes (pigment causing cells).
Low white blood cell count, increased liver enzymes, increased cholesterol, increased serum creatinine.

Drug hypersensitivity reactions such as swelling under the skin and hives have been observed in patients post-marketing.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XELJANZ
- *Storage*

Keep XELJANZ out of the sight and reach of children.

Store XELJANZ below 30°C.

Do not use XELJANZ after the expiry date stated on the carton, bottle, or blister.

Store XELJANZ in its original package in order to protect

from moisture. Do not repackage it.

Do not use this medicine if you notice the tablets show visible signs of deterioration (for example, are broken or discoloured).

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose medicines you no longer use as any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

Product Description

- *What it looks like*

Film-coated tablets:
XELJANZ 5 mg film-coated tablets are white round immediate release film-coated tablet debossed with 'Pfizer' on one side and 'JKI 5' on the other.

Package in foil/foil blister containing 14 or 56 film-coated tablets.

- Some product strengths or pack sizes may not be available in your country

- .*Ingredients*
  - Active ingredient

    Tofacitinib

    The tablets for oral administration contain tofacitinib 5 mg dosage strength.

  - Inactive ingredients

    Tablet Core: Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate.

    Film Coat for 5 mg tablets: Opadry® II White (33G28523) containing HPMC 2910/Hypromellose 6cP, titanium dioxide, lactose monohydrate, macrogol, triacetin (glycerol triacetate).

- *MAL Number*

  XELJANZ FILM-COATED TABLETS 5 MG - MAL14075067AZ

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Date of Revision
22/07/2026

Serial Number
NPRA (R1/3) 09022021/022
NPRA (R1/AI2) 18102022/012

PLD-XELJANZ-0726