

**MEDICATION GUIDE**  
**XELJANZ<sup>®</sup>**  
**(tofacitinib)**  
**tablets, for oral use**

**What is the most important information I should know about XELJANZ?**

**XELJANZ may cause serious side effects including:**

**1. Serious infections.** XELJANZ is a medicine that affects your immune system. XELJANZ can lower the ability of your immune system to fight infections. Some people can have serious infections while taking XELJANZ, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting XELJANZ and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with XELJANZ.

You should not start taking XELJANZ if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).

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

Before starting XELJANZ, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
  - fever, sweating, or chills
  - cough
  - blood in phlegm
  - warm, red, or painful skin or sores on your body
  - burning when you urinate or urinating more often than normal
  - muscle aches
  - shortness of breath
  - weight loss
  - diarrhea or stomach pain
  - feeling very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived, or have traveled to certain places where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you use XELJANZ. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B or C.

After starting XELJANZ, call your healthcare provider right away if you have any symptoms of an infection. XELJANZ can make you more likely to get infections or make worse any infection that you have.

**2. Increased risk of death in people 50 years of age and older with rheumatoid arthritis who have at least 1 heart disease (cardiovascular) risk factor and who**

**are taking a higher than recommended dose of XELJANZ. The recommended dose** in patients with rheumatoid arthritis and psoriatic arthritis is XELJANZ 5 mg twice daily.

**3. Cancer and immune system problems.** XELJANZ may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers including skin cancers can happen in patients taking XELJANZ. People taking the higher dose of XELJANZ (10 mg twice daily) has a higher risk of skin cancers. Tell your healthcare provider if you have ever had any type of cancer.
- Some people who have taken XELJANZ with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr Virus-associated post-transplant lymphoproliferative disorder).

**4. Blood clots in the lungs, veins of the legs or arms, and arteries.** Blood clots in the lungs (pulmonary embolism, PE), veins of the legs (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 daily. 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 healthcare provider 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.

**5. Tears (perforation) in the stomach or intestines.**

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking XELJANZ can get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

**6. Allergic reactions.**

- Symptoms such as swelling of your lips, tongue, or throat, or hives (raised, red patches of skin that are often very itchy) that may mean you are having an allergic reaction have been seen in patients taking XELJANZ. Some of these reactions were serious. If any of these symptoms occur while you are taking XELJANZ, stop XELJANZ and call your healthcare provider right away.

**7. Changes in certain laboratory test results.** Your healthcare provider should do blood tests before you start receiving XELJANZ and while you take XELJANZ to check for the following side effects:

- **changes in lymphocyte counts.** Lymphocytes are white blood cells that help the body fight off infections.
- **low neutrophil counts.** Neutrophils are white blood cells that help the body fight off infections.
- **low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired.

Your healthcare provider should routinely check certain liver tests. You should not receive XELJANZ if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your XELJANZ treatment for a period of time if needed because of changes in these blood test results. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start receiving XELJANZ, and as needed after that. Normal cholesterol levels are important to good heart health. See “What are the possible side effects of XELJANZ?” for more information about side effects.

**What is XELJANZ?**

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is used to treat adults with moderately to severely active rheumatoid arthritis in whom methotrexate did not work well or cannot be tolerated. XELJANZ is used to treat adults with active psoriatic arthritis in which methotrexate or other similar medicines called nonbiologic disease-modifying antirheumatic drugs (DMARDs) did not work well or cannot be tolerated. XELJANZ is used to treat adults with moderately to severely active ulcerative colitis when medicines called tumor necrosis factor (TNF) blockers did not work well or cannot be tolerated. It is not known if XELJANZ is safe and effective in people with Hepatitis B or C. XELJANZ is not recommended for people with severe liver problems. It is not known if XELJANZ is safe and effective in children.

**What should I tell my healthcare provider before taking XELJANZ?**

**Before taking XELJANZ, tell your healthcare provider about all of your medical conditions, including if you:**

- have an infection. See “What is the most important information I should know about XELJANZ?”
- have had blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past.
- have liver problems.
- have kidney problems.
- have any stomach area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have had a reaction to tofacitinib or any of the ingredients in XELJANZ.
- have recently received or are scheduled to receive a vaccine. People who take XELJANZ should not receive live vaccines. People taking XELJANZ can receive non-live vaccines.
- plan to become pregnant or are pregnant. XELJANZ may affect the ability of females to get pregnant. It is not known if this will change after stopping XELJANZ. It is not known if XELJANZ will harm an unborn baby.
- plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take XELJANZ or breastfeed. You should not do both. After you stop your treatment with XELJANZ do not start breastfeeding again until:
  - 18 hours after your last dose of XELJANZ

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XELJANZ and other medicines may affect each other causing side effects.**

**Especially tell your healthcare provider if you take:**

- any other medicines to treat your rheumatoid arthritis, psoriatic arthritis, or ulcerative colitis. You should not take tocilizumab (Actemra<sup>®</sup>), etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>), infliximab (Remicade<sup>®</sup>), rituximab (Rituxan<sup>®</sup>), abatacept (Orencia<sup>®</sup>), anakinra (Kineret<sup>®</sup>), certolizumab (Cimzia<sup>®</sup>), golimumab (Simponi<sup>®</sup>), ustekinumab (Stelara<sup>®</sup>), secukinumab (Cosentyx<sup>®</sup>), vedolizumab (Entyvio<sup>®</sup>), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking XELJANZ. Taking XELJANZ with these medicines may increase your risk of infection.
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take XELJANZ?** Take XELJANZ exactly as your healthcare provider tells you to take it.

- Take XELJANZ 2 times a day with or without food. If you take too much XELJANZ, call your healthcare provider or go to the nearest hospital emergency room right away.
- For the treatment of psoriatic arthritis, take XELJANZ in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.

**What are possible side effects of XELJANZ?**

**XELJANZ may cause serious side effects, including:**

- See “What is the most important information I should know about XELJANZ?”
- **Hepatitis B or C activation infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while you use XELJANZ. Your healthcare provider may do blood tests before you start treatment with XELJANZ and while you are using XELJANZ. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B or C infection:
  - feel very tired
  - little or no appetite
  - clay-colored bowel movements
  - chills
  - muscle aches
  - skin rash
  - skin or eyes look yellow
  - vomiting
  - fevers
  - stomach discomfort
  - dark urine

Common side effects of XELJANZ in rheumatoid arthritis patients and psoriatic arthritis patients include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- diarrhea
- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- high blood pressure (hypertension)

Common side effects of XELJANZ in ulcerative colitis patients include:

- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- increased cholesterol levels
- headache
- upper respiratory tract infections (common cold, sinus infections)
- increased muscle enzyme levels
- rash
- diarrhea

- shingles (herpes zoster)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of XELJANZ. For more information, ask your healthcare provider or pharmacist.

**Call your doctor for medical advice about side effects.**

**How should I store XELJANZ?**

- Please refer to outer packaging for the expiry date and storage condition.
- Safely throw away medicine that is out of date or no longer needed.

**Keep XELJANZ and all medicines out of the reach of children.**

**General information about the safe and effective use of XELJANZ.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use XELJANZ for a condition for which it was not prescribed. Do not give XELJANZ to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about XELJANZ. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about XELJANZ that is written for health professionals.

August 2020  
Hong Kong

## Document Approval Record

**Document Name:**

HKG PIL Tofacitinib - Xeljanz - 5mg & 10mg - 21-AUG-2020

**Document Title:**

New creation of PIL base on USPI (LAB-0535-10.0,DSEC-2019) per B oH query (17-APR-2020)

**Signed By:**

**Date(GMT)**

**Signing Capacity**

Hung, Hoi Yan

26-Aug-2020 05:53:34

Regulatory Affairs Approval