# PATIENT ASSISTANCE PROGRAM APPLICATION

## Patient Application for XELJANZ® XR (tofacitinib) extended release tablets/ XELJANZ® (tofacitinib) tablets

XELSOURCE℠
Answers and Support

Phone 1-844-XELJANZ (1-844-935-5269) • Fax 1-866-297-3471 • 2730 S. Edmonds Lane, Suite 300, Lewisville, TX 75067

**Please complete the form where applicable and return via mail or fax. Pages 1 and 3 must be returned to XELSOURCE.**

☐ **Check here if reapplying for the Pfizer Patient Assistance Program.**

| | | | |
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| **PATIENT INFORMATION** | Patient Name: | | |
| | Patient Address: | | |
| | City: | State: | ZIP Code: |
| | Telephone (Day): | Telephone (Evening): | |
| | E-mail (Please provide to speed up process): | | |
| | Date of Birth (DOB): | | |

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| **INSURANCE INFORMATION** | ☐ I confirm that I do not have prescription drug coverage. |

| | |
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| **PATIENT FINANCIAL INFORMATION** | **Total Number of People Within Household (including applicant):** _____<br>**Total Annual Income for Entire Household: $** _____<br>(The current annual household income includes current annual salary, Social Security, unemployment insurance benefits, and workers' compensation)<br>**Please submit documentation to support the financial information.**<br>**Attached is:** ☐ **Most recent federal tax return (1040 form)** ☐ **W-2 form** ☐ **Other**<br>We must receive proof of income to determine eligibility for assistance.<br>If you are required to file a federal tax return, please provide a signed copy. Proof of income may include documents such as: copy of most recent federal tax return, W-2 form(s), 1099 form, Social Security Award Letter or Check, or copies of three most recent pay stubs. |

**Patient Declaration** – By signing below, I affirm that my answers and my proof-of-income documents are complete, true, and accurate to the best of my knowledge.

**I understand that:**

- Completing this application form does not guarantee that I will qualify for the Pfizer Patient Assistance Program.
- Pfizer may verify the accuracy of the information I have provided and may ask for more financial and insurance information.
- Any medications supplied by the Pfizer Patient Assistance Program shall not be sold, traded, bartered, or transferred.
- Pfizer reserves the right to change or cancel the Pfizer Patient Assistance Program at any time.
- The support provided in this program is not contingent on any future purchase.

**I certify and attest that if I receive medicine(s) provided by the Pfizer Patient Assistance Program:**

- I will promptly contact XELSOURCE if my financial status or insurance coverage changes.
- I will not seek to have the medicine(s) or any cost from it (them) counted in my Medicare Part D out-of-pocket expenses for prescription drugs.
- I will not seek reimbursement or credit for any costs associated with the medicine(s) from my prescription insurance provider or payer, including Medicare Part D plans.
- I will notify my insurance provider of the receipt of any medicine(s) through the Pfizer Patient Assistance Program.
- I have a signed copy of a current and complete HIPAA Authorization Form on record with my Prescriber so that my Prescriber may share health information about me with Pfizer's assistance programs, Pfizer Inc., and the Pfizer Patient Assistance Foundation Inc.

**The information you provide will be used by Pfizer, the Pfizer Patient Assistance Foundation Inc., and parties acting on their behalf to determine eligibility, to manage and improve Pfizer programs, products, and services, to communicate with you about your experience with the Pfizer Patient Assistance Program, and/or to send you materials and other helpful information and updates relating to Pfizer programs. This information may be disclosed to entities to determine eligibility for other patient assistance programs as an alternate or supplement to your coverage for XELJANZ XR or XELJANZ.**

The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation Inc. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc., with distinct legal restrictions.

X _____

**Patient Signature (Parent or Guardian, if under 18 years of age)** **Date**

**Please see Indication and Important Safety Information on page 2. Click here for full Prescribing Information, including BOXED WARNING and Medication Guide.**

## WHAT IS XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ/XELJANZ XR is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well.

XELJANZ/XELJANZ XR 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.

It is not known if XELJANZ/XELJANZ XR is safe and effective in people with hepatitis B or C.

XELJANZ/XELJANZ XR is not recommended for people with severe liver problems.

It is not known if XELJANZ/XELJANZ XR is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about XELJANZ/XELJANZ XR?

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

**Serious infections.** XELJANZ/XELJANZ XR can lower the ability of your immune system to fight infections. Some people can have serious infections while taking XELJANZ/XELJANZ XR, 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 and during XELJANZ/XELJANZ XR treatment, and monitor you closely for signs and symptoms of TB infection during treatment. You should not start taking XELJANZ/XELJANZ XR 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).

- Before starting XELJANZ/XELJANZ XR, 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; or 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 in, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) 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/XELJANZ XR. 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/XELJANZ XR, call your healthcare provider right away if you have any symptoms of an infection. XELJANZ/XELJANZ XR can make you more likely to get infections or make worse any infection that you have.

**Cancer and immune system problems.** XELJANZ/XELJANZ XR may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers, have happened in patients taking XELJANZ/XELJANZ XR. 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).

**Tears (perforation) in the stomach or intestines.** Some people taking XELJANZ/XELJANZ XR can get tears in their stomach or intestine. 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.

**Changes in certain lab test results.** Your healthcare provider should do blood tests before you start receiving XELJANZ/XELJANZ XR, and while you take XELJANZ/XELJANZ XR, 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/XELJANZ XR 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/XELJANZ XR treatment for a period of time if needed because of changes in these blood test results.

Your healthcare provider should do blood tests to check your cholesterol levels 4-8 weeks after you start XELJANZ/XELJANZ XR, and as needed after that.

### What should I tell my healthcare provider before taking XELJANZ/XELJANZ XR?

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

- have an infection
- have liver problems
- have kidney problems
- have any stomach area (abdominal) pain or been diagnosed with diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines, or narrowing within your digestive tract
- have had a reaction to tofacitinib or any of the ingredients in XELJANZ/XELJANZ XR
- have recently received or are scheduled to receive a vaccine. People taking XELJANZ/XELJANZ XR should not receive live vaccines but can receive non-live vaccines
- plan to become pregnant or are pregnant. It is not known if XELJANZ/XELJANZ XR will harm an unborn baby. You should use effective birth control while you are taking XELJANZ/XELJANZ XR and for at least 4 weeks after you take your last dose.

  **Pregnancy Registry:** Pfizer has a registry for pregnant women who take XELJANZ/XELJANZ XR. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking XELJANZ/XELJANZ XR, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll
- plan to breastfeed or are breastfeeding
- **Tell your healthcare provider about all of the medicines you take, especially any other medicines to treat your rheumatoid arthritis or psoriatic arthritis.** You should not take tocilizumab (Actemra®), etanercept (Enbrel®), adalimumab (Humira®), infliximab (Remicade®), rituximab (Rituxan®), abatacept (Orencia®), anakinra (Kineret®), certolizumab pegol (Cimzia®), golimumab (Simponi®), ustekinumab (Stelara®), secukinumab (Cosentyx®), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking XELJANZ/XELJANZ XR. Taking XELJANZ or XELJANZ XR with these medicines may increase your risk of infection.
- Tell your healthcare provider if you are taking 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.

**Taking XELJANZ/XELJANZ XR**

When you take XELJANZ XR, you may see something in your stool that looks like a tablet. This is the empty shell from the tablet after the medicine has been absorbed by your body.

For the treatment of psoriatic arthritis, take XELJANZ/XELJANZ XR in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.

### What are other possible side effects of XELJANZ/XELJANZ XR?

XELJANZ/XELJANZ XR may cause serious side effects, including 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/XELJANZ XR. Tell your healthcare provider if you have 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, or dark urine.

Common side effects of XELJANZ/XELJANZ XR include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, and nasal congestion, sore throat, and runny nose (nasopharyngitis).

**Click here for full Prescribing Information, including BOXED WARNING and Medication Guide.**

XELJANZ® XR
(tofacitinib)
extended release • 11 mg tablets

XELJANZ®
(tofacitinib)
5 mg tablets

Pfizer

# PATIENT ASSISTANCE PROGRAM APPLICATION

## HCP Application for XELJANZ® XR (tofacitinib) extended release tablets/ XELJANZ® (tofacitinib) tablets

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Answers and Support

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| **PRESCRIBER INFORMATION (To be completed by the provider)** | Prescriber Name & Title: | | Prescriber Specialty: | |
| | Payer Specific #: | NPI #: | Tax ID #: | |
| | State License #: | | DEA #: | |
| | Name of Facility: | | | |
| | Prescriber Address: | | | |
| | City: | | State: | ZIP Code: |
| | Contact Name: | | | |
| | Contact Phone: | | Fax: | |
| | Contact E-mail Address: | | | |

**PRESCRIBER CERTIFICATION**

I certify that the information provided is current, complete, and accurate to the best of my knowledge. I will notify XELSOURCE immediately if the Pfizer product is no longer medically necessary for this patient's treatment. **I certify that the Pfizer product is medically necessary for this patient and I will be supervising the patient's treatments.** I have a signed copy on file of my patient's current and completed HIPAA Authorization Form so that I may share patient health information with Pfizer's assistance programs, Pfizer Inc., and the Pfizer Patient Assistance Foundation Inc. I understand that any information provided is for the sole use of Pfizer and their agents and representatives to verify my patient's insurance coverage, to assess, if applicable, patient's eligibility for participation in the Pfizer Patient Assistance Program and to otherwise administer XELSOURCE and related services. I understand that application to the Pfizer Patient Assistance Program does not guarantee that assistance will be obtained. I understand that Pfizer may change or cancel this program at any time. I understand that if my patient's financial and/or insurance status changes, the patient may no longer be eligible for the Pfizer Patient Assistance Program, and I agree to immediately notify a XELSOURCE representative if I become aware of changes in the patient's insurance status. I agree that Pfizer may contact me for additional information relating to this application either by fax or any other form of communication, including but not limited to e-mail and telephone. I understand that I am under no obligation to prescribe any Pfizer product and that I have not received nor will I receive any benefit from Pfizer or their agents or representatives for prescribing a Pfizer product. I agree that I will not submit claims for product provided by the Pfizer Patient Assistance Program.

**The information you provide will be used by Pfizer, the Pfizer Patient Assistance Foundation Inc., and parties acting on their behalf to administer and improve Pfizer programs, products, and services, to communicate with you about your experience with Pfizer and the Pfizer Patient Assistance Program, and/or to send you materials and other helpful information and updates relating to Pfizer programs.**

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| **Prescriber Signature** X | Date: |

| | | | |
|---|---|---|---|
| **SHIP TO** | ☐ Prescriber ☐ Patient ☐ Other (please provide shipping address—NO PHARMACIES): | | |
| | Address: | | |
| | City: | State: | ZIP Code: |

| | | | |
|---|---|---|---|
| **CLINICAL AND PRESCRIPTION INFORMATION** | Patient First Name: | Patient Last Name: | |
| | Patient Date of Birth: | Patient Phone: | |
| | Rx: ☐ XELJANZ XR 11 mg PO QD, 30-day supply ☐ XELJANZ 5 mg PO BID, 30-day supply | | Refills (up to 11): |
| | Drug Allergies: ☐ Yes ☐ No If yes, please list medication(s) and associated reaction(s): | | |
| | | | |
| | Patient's current medication(s): | | |
| | **Prescribing Physician Signature**—NO STAMPS (Dispense as written) | | |
| | X | | Date: |

**Note: If you are a New York prescriber, please attach state prescription form.**

The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation Inc. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc., with distinct legal restrictions.

**Please see Important Safety Information on page 4. Click here for full Prescribing Information, including BOXED WARNING and Medication Guide.**

## INDICATIONS

**Rheumatoid Arthritis**

- XELJANZ/XELJANZ XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).
- Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

**Psoriatic Arthritis**

- XELJANZ/XELJANZ XR (tofacitinib) is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
- Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

## IMPORTANT SAFETY INFORMATION

## BOXED WARNING: SERIOUS INFECTIONS AND MALIGNANCY

**SERIOUS INFECTIONS**

**Patients treated with XELJANZ/XELJANZ XR are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.**

**If a serious infection develops, interrupt XELJANZ/XELJANZ XR until the infection is controlled.**

**Reported infections include:**

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ/XELJANZ XR use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ/XELJANZ XR use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

**The risks and benefits of treatment with XELJANZ/XELJANZ XR should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.**

**Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with XELJANZ/XELJANZ XR, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.**

**MALIGNANCIES**

**Lymphoma and other malignancies have been observed in patients treated with XELJANZ. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with XELJANZ and concomitant immunosuppressive medications.**

### WARNINGS AND PRECAUTIONS

**SERIOUS INFECTIONS**

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Avoid use of XELJANZ/XELJANZ XR in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment before initiating XELJANZ/XELJANZ XR in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis (TB);
- with a history of a serious or an opportunistic infection;
- who have lived or traveled in areas of endemic TB or mycoses; or
- with underlying conditions that may predispose them to infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with XELJANZ/XELJANZ XR. XELJANZ/XELJANZ XR should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis.

Caution is also recommended in patients with a history of chronic lung disease, or in those who develop interstitial lung disease, as they may be more prone to infection.

Risk of infection may be higher with increasing degrees of lymphopenia and consideration should be given to lymphocyte counts when assessing individual patient risk of infection.

**Tuberculosis**

Evaluate and test patients for latent or active infection prior to and per applicable guidelines during administration of XELJANZ/XELJANZ XR. Consider anti-TB therapy prior to administration of XELJANZ/XELJANZ XR in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection. Treat patients with latent TB with standard therapy before administering XELJANZ/XELJANZ XR.

**Viral Reactivation**

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), was observed in clinical studies with XELJANZ. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with XELJANZ/XELJANZ XR. The risk of herpes zoster is increased in patients treated with XELJANZ/XELJANZ XR and appears to be higher in patients treated with XELJANZ in Japan and Korea.

**MALIGNANCY AND LYMPHOPROLIFERATIVE DISORDERS**

Consider the risks and benefits of XELJANZ/XELJANZ XR treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ/XELJANZ XR in patients who develop a malignancy.

In the 7 controlled rheumatoid arthritis clinical studies, 11 solid cancers and 1 lymphoma were diagnosed in 3328 patients receiving XELJANZ with or without DMARD, compared to 0 solid cancers and 0 lymphomas in 809 patients in the placebo with or without DMARD group during the first 12 months of exposure. Lymphomas and solid cancers have also been observed in the long-term extension studies in rheumatoid arthritis patients treated with XELJANZ.

In the 2 controlled Phase 3 clinical trials in patients with active psoriatic arthritis, there were 3 malignancies (excluding NMSC) in 474 patients receiving XELJANZ plus nonbiologic DMARD (6 to 12 months exposure) compared with 0 malignancies in 236 patients in the placebo plus nonbiologic DMARD group (3 months exposure) and 0 malignancies in 106 patients in the adalimumab plus nonbiologic DMARD group (12 months exposure). No lymphomas were reported. Malignancies have also been observed in the long term extension study in psoriatic arthritis patients treated with XELJANZ.

In Phase 2B controlled dose-ranging trials in *de-novo* renal transplant patients, all of whom received induction therapy with basiliximab, high-dose corticosteroids, and mycophenolic acid products, Epstein Barr Virus-associated post-transplant lymphoproliferative disorder was observed in 5 out of 218 patients treated with XELJANZ (2.3%) compared to 0 out of 111 patients treated with cyclosporine.

Other malignancies were observed in clinical studies and the post-marketing setting including, but not limited to, lung cancer, breast cancer, melanoma, prostate cancer, and pancreatic cancer.

**Non-Melanoma Skin Cancer**

Non-melanoma skin cancers (NMSCs) have been reported in patients treated with XELJANZ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

**GASTROINTESTINAL PERFORATIONS**

Gastrointestinal perforations have been reported in XELJANZ clinical trials, although the role of JAK inhibition is not known. XELJANZ/XELJANZ XR should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis).

**LABORATORY ABNORMALITIES**

**Lymphocyte Abnormalities**

Treatment with XELJANZ was associated with initial lymphocytosis at 1 month of exposure followed by a gradual decrease in mean lymphocyte counts of approximately 10% during 12 months of therapy. Counts less than 500 cells/mm$^3$ were associated with an increased incidence of treated and serious infections. Avoid initiation of XELJANZ/XELJANZ XR treatment in patients with a count less than 500 cells/mm$^3$. In patients who develop a confirmed absolute lymphocyte count less than 500 cells/mm$^3$, treatment with XELJANZ/XELJANZ XR is not recommended. Monitor lymphocyte counts at baseline and every 3 months thereafter.

**Neutropenia**

Treatment with XELJANZ was associated with an increased incidence of neutropenia (less than 2000 cells/mm$^3$) compared to placebo. Avoid initiation of XELJANZ/XELJANZ XR treatment in patients with an ANC less than 1000 cells/mm$^3$. For patients who develop a persistent ANC of 500-1000 cells/mm$^3$, interrupt XELJANZ/XELJANZ XR dosing until ANC is greater than or equal to 1000 cells/mm$^3$. In patients who develop an ANC less than 500 cells/mm$^3$, treatment with XELJANZ/XELJANZ XR is not recommended. Monitor neutrophil counts at baseline and after 4-8 weeks of treatment and every 3 months thereafter.

**Anemia**

Avoid initiation of XELJANZ/XELJANZ XR treatment in patients with a hemoglobin level less than 9 g/dL. Treatment with XELJANZ/XELJANZ XR should be interrupted in patients who develop hemoglobin levels less than 8 g/dL or whose hemoglobin level drops greater than 2 g/dL on treatment. Monitor hemoglobin at baseline and after 4-8 weeks of treatment and every 3 months thereafter.

**Liver Enzyme Elevations**

Treatment with XELJANZ was associated with an increased incidence of liver enzyme elevation compared to placebo. Most of these abnormalities occurred in studies with background DMARD (primarily methotrexate) therapy.

Routine monitoring of liver tests and prompt investigation of the causes of liver enzyme elevations is recommended to identify potential cases of drug-induced liver injury. If drug-induced liver injury is suspected, the administration of XELJANZ/XELJANZ XR should be interrupted until this diagnosis has been excluded.

**Lipid Elevations**

Treatment with XELJANZ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Maximum effects were generally observed within 6 weeks.

Assess lipid parameters approximately 4-8 weeks following initiation of XELJANZ/XELJANZ XR therapy, and manage patients according to clinical guidelines for the management of hyperlipidemia.

**VACCINATIONS**

Avoid use of live vaccines concurrently with XELJANZ/XELJANZ XR. The interval between live vaccinations and initiation of tofacitinib therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents. A varicella virus naïve patient experienced dissemination of the vaccine strain of varicella zoster virus 16 days after vaccination with live attenuated virus vaccine which was 2 days after 5 mg twice daily treatment with tofacitinib. The patient recovered after discontinuation of tofacitinib and treatment with antiviral medication. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ/XELJANZ XR therapy.

**GENERAL**

**Specific to XELJANZ XR**

Caution should be used when administering XELJANZ XR to patients with pre-existing severe gastrointestinal narrowing. There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of other drugs utilizing a non-deformable extended release formulation.

**HEPATIC AND RENAL IMPAIRMENT**

Use of XELJANZ/XELJANZ XR in patients with severe hepatic impairment is not recommended.

The recommended dose in patients with moderate hepatic impairment or with moderate or severe renal impairment is XELJANZ 5 mg once daily.

**ADVERSE REACTIONS**

The most common serious adverse reactions were serious infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials with XELJANZ 5 mg twice daily and placebo, respectively, (occurring in greater than or equal to 2% of patients treated with XELJANZ with or without DMARDs) were upper respiratory tract infections (4.5%, 3.3%), headache (4.3%, 2.1%), diarrhea (4.0%, 2.3%), and nasopharyngitis (3.8%, 2.8%).

**USE IN PREGNANCY**

There are no adequate and well-controlled studies in pregnant women and the estimated background risks of major birth defects and miscarriage for the indicated population is unknown. Based on animal studies, tofacitinib has the potential to affect a developing fetus. Women of reproductive potential should be advised to use effective contraception.

## HIPAA Authorization Form for the Disclosure of Patient Information by Personal Physician

## FOR PFIZER INC. AND THE PFIZER PATIENT ASSISTANCE FOUNDATION INC.

## DO NOT SUBMIT THIS FORM WITH YOUR APPLICATION—IT IS FOR PATIENT AND PRESCRIBER RECORDS ONLY

**To the Patient:** Pfizer Inc. and the Pfizer Patient Assistance Foundation, Inc. offer patient assistance programs (the "Program") to help patients who qualify obtain certain Pfizer medicines at no cost. In order to determine your eligibility for the Program and to administer your participation in the Program if you are accepted, Pfizer, along with its affiliated companies and contractors who administer the Program, need to obtain certain information about you from your physician (who is also called your "Doctor" in this form). Please complete this Authorization, sign and date it, and return it to your doctor.

**To the Physician: Please retain the original signed Authorization with the patient's records and provide a copy to the patient. You do not need to return this patient Authorization to Pfizer.**

I request and authorize my Doctor, _____ , to give Pfizer Inc, including representatives and contractors who work on behalf of Pfizer in this Program (collectively, "Pfizer"), my protected health information, including but not limited to information about my medical condition and treatments, which is necessary to determine my eligibility for the Program and for my continuing participation in the Program if I am accepted, to administer the Program, to account for my withdrawal if I decide to stop participating in this Program, and to evaluate patient satisfaction and the Program's overall effectiveness. The type of information that can be given under this authorization may include:

- My name and birth date
- My address and telephone number
- My social security number
- Financial information about me
- Information about my health benefits or health insurance coverage
- Information on my medical condition, as necessary

I understand that I may refuse to sign this authorization and that it is strictly voluntary. Further, I understand that my Doctor may not condition the provision of my treatment on my signing this authorization.

I know that I can cancel (revoke) this authorization at any time by writing to my Doctor at _____. If I cancel this authorization, then my Doctor will stop providing Pfizer, and its representatives, with information about me. However, I cannot cancel actions that have already been taken by relying on my authorization.

I understand that once my Doctor gives Pfizer information about me based on this authorization, federal privacy laws may not prevent Pfizer from further disclosing my information. I also understand that signing this authorization does not guarantee that I will be accepted into a Pfizer patient assistance program.

This authorization will expire one (1) year after the date it is signed, below, or one (1) year after the last date I receive medicines under the Program, whichever is later, or as required by state law.

**Patient or Personal Representative of Patient** {If personal representative, indicate authority to sign on behalf of Patient (if applicable)}

Signature _____

Date _____

Name (please print) _____

***Please return the signed form to your Doctor. You are entitled to a copy for your records.***

**Click here for full Prescribing Information, including BOXED WARNING and Medication Guide.**