PATIENT ASSISTANCE APPLICATION FOR XELJANZ® (tofacitinib citrate) 5 mg tablets

XELSOURCE℠
Answers and Support

Phone 1-855-4-XELJANZ (1-855-493-5526) · Fax 1-866-297-3471 · PO Box 951522, Lake Mary, FL 32795-1522

Please complete the form where applicable and return via mail or fax.

PATIENT INFORMATION	Patient Name:		Sex: Male Female
	Patient Address:		
	City:	State:	ZIP Code:
	Telephone (Day):	Telephone (Evening):	
	E-mail:		
	Date of Birth (DOB):	U.S./Puerto Rico/U.S.V.I. Resident: Yes No	

INSURANCE INFORMATION	Do you have prescription drug coverage? Yes No

PATIENT FINANCIAL INFORMATION	**Total Number of People Within Household (including applicant): _____** **Total Annual Income for Entire Household: $ _____** (The current annual household income includes current annual salary, Social Security, unemployment insurance benefits, and workers' compensation) **Please submit documentation to support the financial information.** **Attached is: Most recent federal tax return (1040 form) W-2 form Other** We must receive proof of income to determine eligibility for assistance. 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 RxPathways™ for XELJANZ Program.
- Pfizer may verify the accuracy of the information I have provided and may ask for more financial and insurance information.
- Any medications supplied with the XELSOURCE Patient Assistance Program shall not be sold, traded, bartered, or transferred.
- Pfizer reserves the right to change or cancel the XELSOURCE 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 Pfizer through the XELSOURCE Patient Assistance Program:

- I will promptly contact the XELSOURCE Patient Assistance Program 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 RxPathways™ for XELJANZ Program.

The information you provide will be used by Pfizer, the Pfizer Patient Assistance Foundation™, and parties acting on their behalf to determine eligibility, to manage and improve Pfizer RxPathways™ (PRxP) programs, products, and services, to communicate with you about your experience with PRxP and the XELSOURCE Patient Assistance Program, and/or to send you materials and other helpful information and updates relating to PRxP 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.

XELSOURCE Patient Assistance Program is part of the Pfizer RxPathways™ family of patient assistance programs – a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation™.

X _____

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

NOTE: Pages 1-6 of this document comprise the patient application. Pages 7-14 provide the full Prescribing Information.

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

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

XELJANZ is not for people with severe liver problems.

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

IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XELJANZ?

XELJANZ may cause serious side effects, including:

Serious infections. XELJANZ can lower the ability of your immune system to fight infections. Some people 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 monitor you closely for signs and symptoms of TB infection during treatment. You should not start taking XELJANZ if you have any kind of infection unless your healthcare provider tells you it is okay.

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; muscle aches; cough; shortness of breath; blood in phlegm; 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; or feeling very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, 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. 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.

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, have happened in patients taking XELJANZ. 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 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, 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.

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

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING XELJANZ?

XELJANZ may not be right for you. Before taking XELJANZ, tell your healthcare provider 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
- have had a reaction to tofacitinib or any of the ingredients in XELJANZ
- have recently received or are scheduled to receive a vaccine. People taking XELJANZ should not receive live vaccines but can receive non-live vaccines
- have any other medical conditions
- plan to become pregnant or are pregnant. It is not known if XELJANZ will harm an unborn baby
  Pregnancy Registry: Pfizer has a registry for pregnant women who take XELJANZ. 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, 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 the medicines you take, especially any other medicines to treat your rheumatoid arthritis. You should not take tocilizumab (Actemra®), etanercept (Enbrel®), adalimumab (Humira®), infliximab (Remicade®), rituximab (Rituxan®), abatacept (Orencia®), anakinra (Kineret®), certolizumab pegol (Cimzia®), golimumab (Simponi®), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking XELJANZ. Taking XELJANZ 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.

WHAT ARE OTHER POSSIBLE SIDE EFFECTS OF XELJANZ?

XELJANZ 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. Tell your healthcare provider if you have the following symptoms of a possible hepatitis B or C infection: feeling very tired, skin or eyes look yellow, little or no appetite, vomiting, clay-colored bowel movements, fevers, chills, stomach discomfort, muscle aches, dark urine, or skin rash.

Common side effects of XELJANZ 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.

Pfizer

XELJANZ®
(tofacitinib citrate)
5 mg tablets

HEALTHCARE PROVIDER APPLICATION FOR XELJANZ® (tofacitinib citrate) 5 mg tablets

Please read all information and print clearly.

XELSOURCE℠
Answers and Support

Please complete the form where applicable and return via mail or fax.

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

PRESCRIBER CERTIFICATION	I certify that the information provided is current, complete, and accurate to the best of my knowledge. I will notify Pfizer RxPathways™ for XELJANZ 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 certify that I have obtained from my patient all required written authorization for the release of my patient's personal identification and insurance information to Pfizer and their agents and representatives. 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 patient assistance program and to otherwise administer the XELSOURCE Patient Assistance Program and related services. I understand that application to the 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 patient assistance program, and I agree to immediately notify a Pfizer RxPathways™ for XELJANZ representative if I become aware of changes in the patient's insurance status. I agree that Pfizer RxPathways™ for XELJANZ 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 Patient Assistance Program. **The information you provide will be used by Pfizer, the Pfizer Patient Assistance Foundation™, and parties acting on their behalf to administer and improve Pfizer RxPathways™ (PRxP) programs, products, and services, to communicate with you about your experience with PRxP and the XELSOURCE Patient Assistance Program, and/or to send you materials and other helpful information and updates relating to PRxP programs.**	
	Prescriber Signature X	Date:

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

CLINICAL AND PRESCRIPTION INFORMATION	First Name:	Last Name:	
	Date of Birth:	Phone:	
	Diagnosis: 714.0 Rheumatoid arthritis (RA) 714.2 Other RA with visceral or systemic involvement Other: _____		
	XELJANZ Rx: 5 mg, 30-day supply PO BID Other: _____		Refills (up to 11):_____
	Allergies, other medications and all medical conditions:		
	Prescribing Physician Signature (Please print-NO STAMPS)		
	Dispense as written X		Date:
	Substitution allowed X		Date:

XELSOURCE Patient Assistance Program is part of the Pfizer RxPathways™ family of patient assistance programs – a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation™.

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

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

Please complete pages 1 and 3 and fax to XELSOURCE at 1-866-297-3471.

INDICATION

- XELJANZ® (tofacitinib citrate) 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 in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

SERIOUS INFECTIONS

Patients treated with XELJANZ 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 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 use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with XELJANZ 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, 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.

SERIOUS INFECTIONS

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, and urinary tract infection. Avoid use of XELJANZ in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment before initiating XELJANZ 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 should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis.

Tuberculosis

Evaluate and test patients for latent or active infection before administration of XELJANZ. Consider anti-TB therapy prior to administration of XELJANZ 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.

Viral Reactivation

Viral reactivation, including cases of herpes virus reactivation (eg, 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.

MALIGNANCY and LYMPHOPROLIFERATIVE DISORDERS

Consider the risks and benefits of XELJANZ 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 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 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.

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 rheumatoid arthritis clinical trials, although the role of JAK inhibition is not known. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. XELJANZ should be used with caution in patients who may be at increased risk for gastrointestinal perforation (eg, 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 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 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 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 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 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 treatment in patients with a hemoglobin level less than 9 g/dL. Treatment with XELJANZ 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 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 therapy, and manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines concurrently with XELJANZ. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ therapy.

HEPATIC IMPAIRMENT

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

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. XELJANZ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

XELSOURCE℠
Answers and Support

HIPAA Authorization Form for the Disclosure of Patient Information

To PATIENT:

The attached Authorization is for you and your doctor. If you sign this Authorization, you are allowing your doctor to give Pfizer health information about you that will help you get your Pfizer medications. An example of the type of information we need from your doctor would be the prescription for the medicine you need. This Authorization is between you and your doctor only. **Please sign and give your doctor the original signed Authorization and keep a copy for your records. This form should not be returned with your application.**

To PHYSICIAN:

The attached Authorization, when signed by your patient, documents the patient's permission for you to share certain medical and personal information with Pfizer in connection with Pfizer's patient assistance programs. **This Authorization is strictly for your records and should not be returned with your patient's application.**

To PATIENT and PHYSICIAN, please note:

XELSOURCE is powered by Pfizer RxPathways™. Pfizer RxPathways™ is a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation™.

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

XELSOURCE℠
Answers and Support

HIPAA Authorization Form for the Disclosure of Patient Information

To the Patient: 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, _____ ("Doctor"), to give Pfizer Inc, its affiliates, agents and service providers who work on behalf of Pfizer (including but not limited to United BioSource LLC, its affiliates, and specialty pharmacies), information about me and my medical condition, which is necessary to determine my eligibility for XELSOURCE support services and for my continuing participation in XELSOURCE if I am accepted, to administer XELSOURCE, to account for my withdrawal if I decide to stop participating in XELSOURCE, and to evaluate patient satisfaction and the overall effectiveness of XELSOURCE. 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 know that I can cancel this Authorization at any time by writing to my Doctor at:

Address: _____

City: _____ State: _____ ZIP Code: _____

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 Inc, its affiliates, agents and service providers who work on behalf of Pfizer (including but not limited to United BioSource LLC, its affiliates, and specialty pharmacies) information about me based on this Authorization, federal privacy laws may not prevent Pfizer from further disclosing my information to other entities to determine eligibility for other patient assistance programs as an alternate or supplement to my coverage for XELJANZ. 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.

Patient or Personal Representative of Patient (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 accompanying full Prescribing Information, including BOXED WARNING and Medication Guide.