

Please see Indication and Important Safety Information on page 2. [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<sup>3</sup> 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<sup>3</sup>. In patients who develop a confirmed absolute lymphocyte count less than 500 cells/mm<sup>3</sup>, 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<sup>3</sup>) compared to placebo. Avoid initiation of XELJANZ/XELJANZ XR treatment in patients with an ANC less than 1000 cells/mm<sup>3</sup>. For patients who develop a persistent ANC of 500-1000 cells/mm<sup>3</sup>, interrupt XELJANZ/XELJANZ XR dosing until ANC is greater than or equal to 1000 cells/mm<sup>3</sup>. In patients who develop an ANC less than 500 cells/mm<sup>3</sup>, 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.

# PATIENT COPY

## PROVIDER INSTRUCTIONS

- 1 Have the patient read this form and sign the acknowledgement on the front of the Prescription Information and XELSOURCE<sup>SM</sup> Enrollment Form (P&E Form) relating to the Patient Authorization and XELSOURCE Extended Services Enrollment Information.
- 2 Provide the patient with this sheet and a copy of the front and back of the P&E Form which they have signed.
- 3 Fax the P&E Form to XELSOURCE at 1-866-297-3471.

## PATIENT AUTHORIZATION (PA)

My signature on the front of the Prescription Information and XELSOURCE Enrollment Form confirms that:

### 1. Disclosure of Protected Health Information to Pfizer Inc for XELSOURCE

I authorize each of my physicians, pharmacists, including any specialty pharmacy that receives my prescription, and other healthcare providers (together, "Healthcare Providers") and each of my health insurers (together, "Insurers") to disclose my protected health information, including but not limited to information and medical records related to my medical condition and treatment associated with my prescription for XELJANZ<sup>®</sup> XR (tofacitinib) extended release/XELJANZ<sup>®</sup> (tofacitinib); my health insurance coverage; and my name, address, telephone number, Social Security number, insurance plan and/or group numbers (together, "Protected Health Information") to Pfizer Inc and its present or future affiliates, agents and representatives, including providers of alternate sources of funding for prescription drug costs, and other service providers (including but not limited to Cardinal Health, and its affiliates, and specialty pharmacies) supporting XELSOURCE and other Pfizer Inc patient assistance programs (together, "Pfizer Inc" or the "Pfizer Patient Assistance Foundation").

Specifically, I authorize Pfizer Inc to receive, use, and disclose my Protected Health Information in order to: (i) enroll me in XELSOURCE and contact me, and/or the person legally authorized to sign on my behalf, about XELSOURCE; (ii) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to XELJANZ XR/XELJANZ; (iii) verify, investigate, assist with, and coordinate my coverage for XELJANZ XR/XELJANZ, including but not limited to communicating with my Insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; (iv) coordinate prescription fulfillment; and (v) assist with analyses related to XELJANZ XR/XELJANZ.

### 2. Use of Protected Health Information to Provide Marketing Communications and Information Related to XELSOURCE

I authorize any specialty pharmacy that receives my prescription to use my Protected Health Information to provide me with marketing communications and information related to XELSOURCE, including providing certain adherence messages. I acknowledge that these specialty pharmacies may receive compensation from Pfizer Inc for their services and costs incurred in connection with providing such marketing communications and information.

I understand that my Protected Health Information will not be used or disclosed by Pfizer Inc for any purposes other than as described here, unless permitted or required by law, or unless information that specifically identifies me is removed.

I understand that Pfizer Inc will make every effort to keep my Protected Health Information private. Nonetheless, I understand that once my Protected Health Information has been disclosed to Pfizer, it may no longer be protected by the federal privacy standards. Further, I understand that if the authorized recipient is not a provider, health plan, or clearinghouse required to comply with federal privacy standards, the information disclosed pursuant to this authorization may no longer be protected by the federal privacy standards. If my information is accidentally shared, federal privacy laws do not require that the person/party receiving it not disclose the information further. Information disclosed under these circumstances and provided to a third party may no longer be protected by federal privacy laws.

I understand that I am not required to sign this Patient Authorization. My choice about whether to sign will not change the way my Healthcare Providers furnish treatment to me nor will it alter my eligibility for benefits offered by my Insurers. However, if I refuse to sign this Authorization, or revoke my authorization later, I understand that this means I will not be able to participate in or receive assistance from XELSOURCE.

This Authorization will expire ten (10) years after the date it is signed on the front of the Prescription Information and XELSOURCE Enrollment Form. I understand that I may cancel (revoke) this Authorization at any time by mailing a letter to XELSOURCE, 2730 S. Edmonds Lane, Suite 300, Lewisville, TX 75067. I can also revoke my authorization by informing my Healthcare Providers and Insurers in writing that I do not want them to share any information with Pfizer Inc, but this will not affect Pfizer Inc's ability to use and disclose Protected Health Information that was already disclosed to it under this Authorization.

Furthermore, I understand that I have the right to see or copy the Protected Health Information my Healthcare Providers or Insurers have disclosed to Pfizer Inc.

### XELSOURCE EXTENDED SERVICES ENROLLMENT INFORMATION

By signing the front of the Prescription Information and XELSOURCE Enrollment Form, I agree to allow Pfizer Inc, or parties acting on its behalf, to send me materials and other helpful information on rheumatoid arthritis and XELJANZ XR/XELJANZ, as well as related treatments, products, offers, and services.

To support the extended services program, your name, address, and other information that you give us will be used by Pfizer Inc, the marketer of XELJANZ XR/XELJANZ, and companies that work with Pfizer Inc, including vendors and other affiliates, to support the Program.

Pfizer Inc understands that your personal health information is private. Pfizer Inc will not share your information with anyone else except as stated above and as required by law. If you want to stop receiving this information from Pfizer Inc, you may ask us to remove you from our contact list by calling 1-844-XELJANZ (1-844-935-5269).

**Please read the Indication and Important Safety Information for XELJANZ XR/XELJANZ on page 2, and discuss any questions you have with your doctor.**



## Trial Rx Terms & Conditions

- This is not health insurance and is a one-time offer for eligible, commercially insured patients only.
- Offer is only available to patients who have been diagnosed with an FDA-approved indication for XELJANZ<sup>®</sup> XR (tofacitinib) extended release/XELJANZ<sup>®</sup> (tofacitinib).
- Patients who have already begun therapy with XELJANZ XR/ XELJANZ at the time of the request and patients under the age of eighteen (18) years of age are ineligible for participation in the Program.
- No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer.
- Not available to patients covered under government plans such as Medicaid, Medicare or other federal or state healthcare programs, including any state prescription drug assistance programs and the Government Health Insurance Plan or for residents of Massachusetts, Michigan, Minnesota, Missouri, Ohio, or Rhode Island.
- Available in a 14-day supply.
- This offer does not require, nor will be made contingent on, purchase requirements of any kind.
- Pfizer reserves the right to amend, rescind, or discontinue this program at any time without notification.
- Trial Rx can only be dispensed by the exclusive pharmacy and only after benefits investigation has been completed.
- Offer good only in the US and Puerto Rico.
- Prescription must be provided by a healthcare provider licensed in the US or Puerto Rico.
- Additional eligibility criteria may apply, contact XELSOURCE for details.

## Disclaimer

Pfizer's service provider performing XELSOURCE support services provides patient insurance benefit verification as a service under contract for Pfizer Inc. XELSOURCE support services assists patients in the determination of whether treatment could be covered by the applicable third-party payer based on coverage guidelines provided by the payer and patient information provided by the healthcare provider under appropriate authorization following the provider's exclusive determination of medical necessity.

Many factors affect third-party reimbursement. Pfizer Inc and Pfizer's service provider performing the XELSOURCE support services make no representation or guarantee that insurance reimbursement or any other payment will be available. This information is provided as an information service only. While Pfizer's service provider performing XELSOURCE support services tries to provide correct information, it and Pfizer Inc make no representations or warranties, expressed or implied, as to the accuracy of the information. The support services administrator, or Pfizer Inc, or its employees or agents shall in no event be liable for any damages resulting from or relating to the services. Responsibility for the use of this service is agreed upon and accepted by all providers and other users of this information.

Pfizer Inc does not guarantee, and assumes no responsibility for, the quality, scope, or availability of the XELSOURCE support services including but not limited to reimbursement support services, patient education, and other support services. XELSOURCE support services are included within the cost of the product, and have no independent value.

## Interim Care Rx Terms & Conditions

- This is not health insurance and is available for eligible, commercially insured patients only.
- Offer is only available to patients who have been diagnosed with an FDA-approved indication for XELJANZ XR/XELJANZ.
- No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer.
- Not available to patients covered under government plans such as Medicaid, Medicare or other federal or state healthcare programs, including any state prescription drug assistance programs and the Government Health Insurance Plan or for residents of Massachusetts, Michigan, Minnesota, Missouri, Ohio, or Rhode Island.
- Available in 14- and 28-day supplies, refills subject to limitations.
- This offer does not require, nor will be made contingent on, purchase requirements of any kind.
- Pfizer reserves the right to amend, rescind, or discontinue this program at any time without notification.
- Interim Care Rx can only be dispensed by the exclusive pharmacy and only after benefits investigation has been completed and a delay occurs in the prior authorization or appeals process.
- Interim Care refills will continue until a coverage determination has been made by the health plan. If denied, the patient may be eligible for Hardship support.
- Offer good only in the US and Puerto Rico.
- Prescription must be provided by a healthcare provider licensed in the US or Puerto Rico.
- Additional eligibility criteria may apply, contact XELSOURCE for details.

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