Your treatment with XELJANZ®▼ (tofacitinib citrate) for psoriatic arthritis

THIS BROCHURE HAS BEEN PRODUCED FOR PATIENTS WHO HAVE BEEN PRESCRIBED XELJANZ FOR THE TREATMENT OF PSORIATIC ARTHRITIS.

BEFORE USING XELJANZ, PLEASE REVIEW THE PACKAGE LEAFLET FOR THIS MEDICINAL PRODUCT.

Pfizer

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects, or search for MHRA Yellow Card in the Google Play or Apple App Store.

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Dear Patient,

Your doctor has prescribed you with a medicine called XELJANZ for the treatment of psoriatic arthritis.

This brochure contains information on how XELJANZ works and how to take it, as well as things to look out for before and during your treatment.

Please keep in mind that the information in this brochure is not a replacement for the advice given to you by your doctor. If you have any doubts or questions, please consult your doctor or pharmacist.

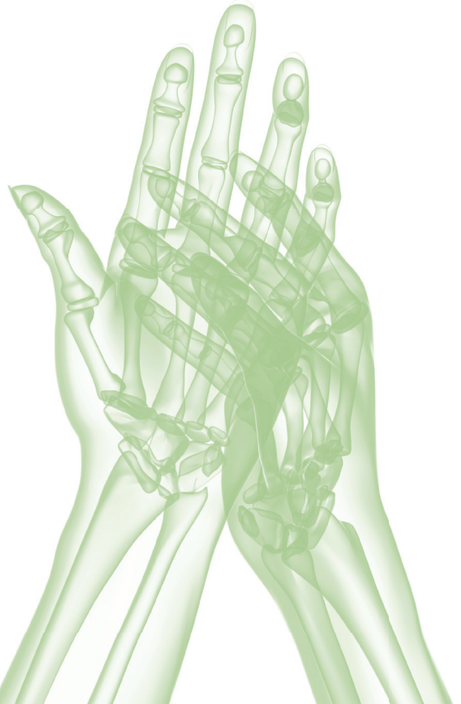
Contents

What is psoriatic arthritis (PsA)?

PsA is a chronic (long-term) inflammatory arthritis. It often affects people who have psoriasis, a condition that occurs when the immune system attacks the skin. Psoriasis can result in red and white scaly patches on the skin.

Symptoms of PsA include painful, stiff and swollen joints, though the symptoms vary. They may also include inflammation in the tendons, fingers or toes, as well as the skin.

Your doctor can advise you on the best way to control the condition over time.



What is XELJANZ?

XELJANZ contains the active substance tofacitinib citrate, which blocks the activation of parts of the immune system responsible for inflammation. By inhibiting inflammation, XELJANZ helps to reduce symptoms, such as pain and swelling.

Your doctor will prescribe XELJANZ in combination with methotrexate (MTX) to treat adult patients with active PsA who have not responded to, or who are intolerant to disease modifying antirheumatic drugs (DMARDs).

XELJANZ is an oral medication and is available in 5 mg tablets. Your doctor will discuss the dosage with you.

Like all medicines, XELJANZ can result in side effects, although not everyone experiences them. See page 14 of this brochure and refer also to the package leaflet that comes with XELJANZ.

The pack shown does not represent the actual size.

What you need to know before starting treatment with XELJANZ

You must not take XELJANZ if:

- You are allergic to the active substance tofacitinib citrate or any other ingredient of XELJANZ
- You have a severe infection, such as sepsis or active tuberculosis (TB)
- You have been informed that you have severe liver impairment, including cirrhosis (scarring of the liver)
- You are pregnant or breastfeeding

Please refer to the package leaflet to find out when to contact your doctor before taking XELJANZ.

XELJANZ film-coated tablets contain lactose. Patients who suffer from rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take XELJANZ film-coated tablets.

Your doctor has prescribed XELJANZ. Please inform your doctor if:

- You think you have an infection or have symptoms of an infection, such as fever, sweating, chills, muscle aches, cough, shortness of breath, new phlegm or change in phlegm, weight loss, warm or red or painful skin or sores on your body, difficulty or pain when swallowing, diarrhoea or stomach pain, burning when you urinate or urinating more often than normal or feeling very tired
- You have any condition that increases your risk of infection (e.g. diabetes, HIV/AIDS or a weak immune system)
- You feel unwell. XELJANZ can reduce your body's ability to respond to infections and may worsen an existing infection or increase the risk of getting a new infection
- You have ongoing TB, have a history of TB or have been in close contact with someone with TB. Your doctor will test you for TB before starting XELJANZ and may retest during treatment
- You have any chronic lung disease, including interstitial lung disease
- You have liver problems

Your doctor has prescribed XELJANZ. Please inform your doctor if:

- You have or have had hepatitis B or C (viruses that affect the liver). The virus may become active while you are taking XELJANZ. Your doctor may do blood tests for hepatitis before you start treatment with XELJANZ and while you are taking XELJANZ
- You have ever had any type of cancer. XELJANZ may increase your risk of certain cancers. Lymphoma and other cancers (e.g. lung, breast, melanoma, prostate and pancreatic) have been reported in patients treated with XELJANZ. If you develop cancer while taking XELJANZ your doctor will review whether to stop XELJANZ treatment
- You are a current or past smoker
- You are at high risk of developing skin cancer. Your doctor may recommend that you have regular skin examinations while taking XELJANZ
- You have had an inflammation of the large intestine (diverticulitis) or ulcers in stomach or intestines
- You have kidney problems
- You are planning to get vaccinated. Certain types of vaccines should not be given at the same time as taking XELJANZ. Before you start XELJANZ, you should be up to date with all recommended vaccinations
- You are planning to have surgery or a medical procedure. Your doctor will decide if you can be given XELJANZ
- You have heart problems, high blood pressure or high cholesterol
- You are at risk of blood clots. There have been reports of patients treated with XELJANZ who have developed blood clots in the lungs or veins. Your doctor will evaluate your risk of developing blood clots in the lungs or veins and determine if XELJANZ is appropriate for you. If you have already experienced problems with developing blood clots in lungs and veins or have an increased risk for developing this (e.g. if you are seriously overweight (BMI ≥30), if you have cancer, heart problems, diabetes, experienced a heart attack within previous 3 months, recent major surgery, if you use hormonal contraceptives/hormone replacement therapy or if a coagulation defect is identified in you or your close relatives), or if you are of older age (over 65 years of age), or you smoke, your doctor may decide that XELJANZ is not suitable for you
- Talk to your doctor immediately if you develop sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness or redness or discolouration in the leg or arm while taking XELJANZ, as these may be symptoms of a clot in the lungs or veins

How to take XELJANZ

The recommended dose is 5 mg twice a day*

XELJANZ may only be taken on a doctor's prescription. Always take XELJANZ exactly as described in the package leaflet, or as your doctor has instructed. Check with your doctor or pharmacist if you are not sure.

Your doctor may reduce the dose of XELJANZ if you have liver or kidney problems, or if you are prescribed certain other medicines. You might also have to stop taking XELJANZ temporarily or permanently if blood tests show low white or red blood cell counts.

***5 mg twice a day**

Tablet does not represent actual size.

Tips for taking your medicine

- Take XELJANZ exactly as prescribed by your doctor
- You can take your tablet **with or without food**
- **If you accidentally take more XELJANZ than you should**, inform your doctor or pharmacist **immediately**
- **If you forget to take your tablet**, do not take two doses at the same time to make up for a forgotten tablet. Take your next tablet at the usual time and continue as before
- **You should not stop your treatment or change the prescribed dosage** without first consulting your doctor

Take XELJANZ exactly as prescribed by your doctor

XELJANZ has been prescribed to you by a doctor who specialises in treating PsA. Always take XELJANZ as instructed by your doctor. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe the dose of XELJANZ that is right for you. Do not change the dose of XELJANZ that has been prescribed or stop taking XELJANZ without talking to your doctor first. If you have questions or concerns about your medication, talk to your doctor or pharmacist.

Other important information

- Do not use the medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month
- No special temperature storage conditions are required. Store in the original package to protect from moisture
- Keep out of the sight and reach of children
- Do not use this medicine if you notice the tablets show visible signs of deterioration (e.g. broken or discoloured)
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment

Pregnancy and breastfeeding

During pregnancy or breastfeeding, XELJANZ should not be used.

Speak to your doctor if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

If you are a woman of childbearing potential, you should use effective birth control during treatment with XELJANZ and for at least 4 weeks after the last dose.

Possible side effects of XELJANZ

Like all medicines, XELJANZ can cause side effects, although not everybody gets them

Speak to your doctor **immediately** if you experience:

- Signs of serious infections, such as fever and chills, cough, skin blisters, stomach ache or persistent headaches
- Symptoms of allergic reactions, such as chest tightness, wheezing, severe dizziness, light-headedness, itching, skin rash, or swelling of the lips, tongue or throat
- Sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, redness or discolouration in the leg or arm

Side effects that have been observed with XELJANZ:

Common ADRs (≥1/100 to <1/10)

Lung infection (pneumonia and bronchitis), shingles (herpes zoster), influenza, sinusitis, urinary bladder infection (cystitis), infections of nose, throat or the windpipe (nasopharyngitis), sore throat (pharyngitis), increased muscle enzymes in the blood (signs of muscle problems), stomach (belly) pain (which may be from inflammation of the stomach lining), vomiting, diarrhoea, feeling sick (nausea), indigestion, joint sprain, low red blood cell count (anaemia), fever, fatigue (tiredness), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash.

ADR=adverse drug reaction.

Side effects that have been observed with XELJANZ:

Uncommon ADRs (≥1/1,000 to <1/100)

TB, kidney infection, skin infection, herpes simplex or cold sores (oral herpes), low white blood cell counts, increased liver enzymes in the blood (sign of liver problems), blood creatinine increased (a possible sign of kidney problems), increased cholesterol, weight gain, dehydration, muscle strain, pain in the muscles and joints, tendonitis, joint swelling, abnormal sensations, sinus congestion, poor sleep, shortness of breath or difficulty breathing, venous thromboembolism, myocardial infarction, skin redness, itching, fatty liver, painful inflammation of small pockets in the lining of your intestine (diverticulitis), viral infections, viral infections affecting the gut, lung cancer, some types of skin cancers (non-melanoma types).

Rare ADRs (≥1/10,000 to <1/1000)

Blood infection (sepsis), lymphoma (white blood cell cancer), TB involving bones and other organs, and joint infections.

Very rare ADRs (<1/10,000)

TB involving the brain and spinal cord, meningitis.

If you notice any side effects, including side effects not listed in this brochure, talk to your doctor or pharmacist.

ADR=adverse drug reaction.

What you should be aware of during your treatment with XELJANZ

Additional monitoring tests

Your doctor will perform blood tests at the following times to check that your white and red blood cell levels are satisfactory:

- Before you start treatment with XELJANZ
- From 4–8 weeks after start of treatment
- Every 3 months thereafter

These tests help monitor for any risk of infection or other problems, such as anaemia.

Your doctor may conduct other tests, such as checking your blood cholesterol or monitoring the health of your liver. Your doctor should test your cholesterol levels 8 weeks after initiation of treatment and perform liver tests periodically.

What you should remember when taking XELJANZ

- XELJANZ contains the active substance tofacitinib citrate, which blocks the activation of parts of the immune system which are involved in PsA
- Before taking XELJANZ, it is important that you discuss your state of health with your doctor
- Always take this medicine exactly as your doctor has instructed. If you are not sure, please refer to the package leaflet that came with your medication, or check with your doctor or pharmacist
- During your treatment with XELJANZ, tell your doctor immediately if you notice any side effects
- To carry the Patient Alert Card (PAC) attached to this brochure with you

Notes

Patient Alert Card

XELJANZ Patient Alert Card to be inserted here

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

The persons depicted in this brochure are for illustrative purposes only and are not actual patients or doctors.

This brochure has been written and published by Pfizer for people with psoriatic arthritis. For more information about XELJANZ, we recommend you also read the package leaflet carefully before using this medication.