

The image features two hands, palms facing each other, with a semi-transparent skeletal overlay showing the bones of the fingers, wrists, and forearms. The hands are set against a large, stylized 'X' shape that is filled with a gradient from dark red to white. The overall background is white.

PATIENT ALERT CARD

Version: 4.0
Date of approval: 28/01/2022

XELJANZ[®] 
[tofacitinib]

The logo graphic consists of several red, hand-like shapes of varying lengths radiating from a central point, resembling a fan or a stylized sunburst.



PATIENT ALERT CARD

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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- This card contains important safety information that you need to be aware of before you start taking XELJANZ and during your treatment with XELJANZ. If you do not understand this information, please ask your doctor/pharmacist to explain it to you.
- Keep this card with you and show it to any doctor or pharmacist involved in your care.
- See the XELJANZ package leaflet for more information. You should use XELJANZ following the package leaflet.

Tell your doctor or your pharmacist about ALL the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Some medicines should not be taken with XELJANZ as they could alter the level of XELJANZ in your body and your dose may require adjustment. You should tell your doctor if you are using medicines that contain the following active substances:

- antibiotics such as rifampicin, used to treat bacterial infections
- fluconazole and ketoconazole used to treat fungal infections

XELJANZ is not recommended for use with biologic DMARDs for rheumatoid arthritis or psoriatic arthritis, biologics for ulcerative colitis, or with certain other medicines that depress your immune system (e.g., azathioprine, mercaptopurine, tacrolimus or ciclosporine). Taking XELJANZ with these medicines may increase your risk of immunosuppression and infection.

XELJANZ may increase your risk of getting infections, which can become serious if not treated. You may be at higher risk for infections if you are

65 years of age or older, have diabetes, chronic lung disease, or are taking corticosteroids. Your XELJANZ treatment may be stopped by your doctor.

There have been reports of patients treated with XELJANZ who have had a heart problem. Tell your doctor if you have heart problems, high blood pressure, high cholesterol and also if you are a current or past smoker. Your doctor will evaluate your risk to develop a heart problem and determine if XELJANZ is appropriate for you.

XELJANZ may increase your risk of certain cancers. White blood cell cancer, lung cancer and other cancers have been reported in patients treated with XELJANZ. Tell your doctor if you have ever had any type of cancer, and also if you are a current or past smoker. Your doctor will evaluate your risk to develop cancer and determine if XELJANZ is appropriate for you. If you develop cancer while taking XELJANZ, your doctor will review whether to stop XELJANZ treatment.

Treatment with XELJANZ may increase your risk of non melanoma skin cancer.

During treatment with XELJANZ

Tell 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 discoloration in the leg or arm while taking XELJANZ, as these may be signs of a clot in the lungs or veins.
- Develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness.
- Develop any symptoms of herpes zoster, such as painful skin rash or blisters.
- Have been in close contact with a person with tuberculosis.
- Develop severe chest pain or tightness (that may spread to arms, jaw, neck and back), shortness of breath, cold sweat, light headedness or sudden dizziness.
- Develop any swelling of lymph nodes in your neck, armpits, or groin; constantly feeling tired; fever; night sweats; persistent or worsening cough; difficulty breathing; hoarseness or wheezing; or unexplained weight loss.
- Notice any new growth on the skin or any changes in existing moles or spots.

- Develop symptoms of interstitial lung disease, such as shortness of breath.
- Develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits with fever.
- Develop yellow skin, nausea or vomiting.
- Are due to receive any vaccine. You should not receive certain types of vaccines while taking XELJANZ.
- Become pregnant or plan on becoming pregnant. XELJANZ must not be used during pregnancy. Women of childbearing potential should be advised to use effective contraception during treatment with XELJANZ and for at least 4 weeks after the last dose.
- Women must not breast-feed while being treated with XELJANZ.

Other Information *(please complete)*

Patient's Name: _____

Doctor's Name: _____

Doctor's Phone: _____

Doctor's Fax: _____

If you stop taking XELJANZ, keep this card with you for at least 2 months after taking the last dose of XELJANZ.

