PATIENT ALERT CARD

XELJANZ®▼
(tofacitinib citrate)

- 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 your healthcare provider, including any emergency staff, who may be treating you apart from your specialist. It's important you make them aware that you are taking XELJANZ to treat your condition.**
- See the XELJANZ patient information leaflet for more information. You should use XELJANZ following the information within the patient information 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.

There is a possibility that you may experience more side-effects when you are given XELJANZ and another medicine called methotrexate at the same time.

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.

* *DMARD=disease-modifying antirheumatic drug.*

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 and determine if XELJANZ is appropriate for you. If you ever had blood clots in lungs and veins or if you have an increased risk for developing blood clots (for example, if you have cancer, if you have heart problems, if you experienced a heart attack within previous 3 months, if you use hormonal contraceptives\hormonal replacement therapy, if you had recent major surgery, or if you or a close relative has a coagulation defect), your doctor may decide that XELJANZ is not suitable for you.

There have been reports of patients treated with XELJANZ who have had a heart problem, including heart attack. 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 of developing 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 of developing 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 discolouration in the leg or arm while taking XELJANZ, as these may be signs of a clot in the lungs or veins.
- 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, as these may be signs of a heart attack.
- 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 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 use effective contraception during treatment with XELJANZ and for at least 4 weeks after the last dose.
- Women must not breastfeed while being treated with XELJANZ.

Other Information (please complete)

Patient's name:

Doctor's name:

Doctor's phone:

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

▼ 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 via HPRA Pharmacovigilance. Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

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