

Patient Alert Card

- important safety information

▼ **XELJANZ[®]**
(tofacitinib)



- ▼ 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.legemiddelverket.no/pasientmelding

- 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 are unsure of this information, please ask your doctor/ pharmacist to explain it to you.
- Keep this card with you and show it to any health care personnel involved in your care.
- For more information, please refer to the Xeljanz package leaflet in the pack or at www.felleskatalogen.no. Use Xeljanz as described in the package leaflet, unless your doctor has told you otherwise.

Tell your doctor and pharmacist about ALL the medicines you are taking, 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.

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 medicines for the treatment of rheumatoid arthritis, psoriatic arthritis or ulcerative colitis. Nor is Xeljanz recommended for use with certain other medicines that depress your immune system (for instance azathioprine, mercaptopurine, tacrolimus or ciclosporin). 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 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.

Other information (please fill in):

Patient: _____

Doctor: _____

Doctor's phone: _____

If you stop taking Xeljanz, you should keep this card with you for at least 2 months after taking the last dose. Date: _____

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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. 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 shingles (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 shortness of breath or breathing problems. These may be symptoms of interstitial lung disease.
- Develop signs and symptoms of abdominal problems, such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits combined with fever.

- Develop yellow skin, nausea or vomiting.
- Plan to have a vaccine. Certain vaccines should not be taken while using Xeljanz.
- Become pregnant or plan on becoming pregnant. Do not use Xeljanz during pregnancy. If you are a woman of childbearing age, you should use effective contraception during treatment with Xeljanz and for at least 4 weeks after the last dose.
- Are breastfeeding. Do not breastfeed while you are being treated with Xeljanz.

Important information for health care personnel:

The carrier of this card uses Xeljanz. It is important to take this into consideration with all treatment.

For more information than what is given in this card, please see the product information (preparatomtale, SPC) found at www.legemiddelsok.no