



- 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.
- Develop any symptoms of herpes zoster, such as painful skin rash or blisters.
- Have been in close contact with a person with tuberculosis.
- Notice any new growth on the skin or any changes in existing moles or spots.

Monitoring

- It is recommended to have blood tests according to the physician's orders before you start receiving Xeljanz and while you take Xeljanz to check for the following side effects:
- **Changes in lymphocyte counts.** Lymphocytes are white blood cells that help the body fight off infections. Lymphocytes should be monitored at baseline, and every 3 months thereafter.
- **Low neutrophil counts.** Neutrophils are white blood cells that help the body fight off infections. Neutrophils should be monitored at baseline and after

4-8 weeks of treatment and every 3 months thereafter.

- **Low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired. Red blood cell count (hemoglobin) should be monitored at baseline and after 4-8 weeks of treatment and every 3 months thereafter.
- Certain liver tests should be routinely tested.
- You should not receive Xeljanz if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high.
- People who take Xeljanz should not receive live vaccines. People

taking Xeljanz can receive non-live vaccines.

REPORTING OF SUSPECTED ADVERSE REACTIONS

Adverse events can be reported directly to the Ministry of Health using the adverse events digital form which is available on the home page of the Ministry of Health website: www.health.gov.il

or by this link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

Side effects can also be reported to Pfizer by email:
isr.aereporting@pfizer.com

This card and its content approved by the Ministry of Health, January 2019

XELJANZ[®] Patient Safety Information Card

The bearer of this card
is treated with Xeljanz[®]
for Ulcerative Colitis



The Bearer of this card is treated with Xeljanz® for Ulcerative Colitis

Patient's Name:
Doctor's Name:
Doctor's Phone:
Date of treatment commencement:
Dosage:

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What XELJANZ is and what it is used for

Xeljanz is a medicine that contains the active substance tofacitinib which works by blocking the action of enzymes known as Janus kinases.

How to Take XELJANZ

- The recommended dose is 10 mg twice a day for 8 weeks, followed by 5 or 10 mg twice a day depending on your therapeutic response.
- Your doctor may decide to stop Xeljanz if Xeljanz does not work for you within 16 weeks.
- The dose of Xeljanz should be adjusted if you have liver or kidney problems or if you are

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prescribed certain other medicines. In addition, treatment should be temporarily or permanently stopped if blood tests show low white blood cell or red blood cell counts.

- Notify your physician if you are taking or have recently taken other medications, including non-prescription medications and dietary supplements, if you have liver or kidney problems and regarding any changes in your medical conditions.
- If you forget to take this medicine at the appropriate time, do not take a double dose. Take the next dose at the usual time and tell your doctor. Treatment should be continued as recommended by the doctor.

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Adverse events that can occur to you during treatment with XELJANZ

- This card contains selected safety information that you need to be aware of before you start taking Xeljanz and during your treatment with Xeljanz. For a full list of side effects, see the consumer leaflet.

Serious infections including Herpes Zoster

- Xeljanz can lower the ability of your immune system to fight infections. Some people can have serious infections while taking Xeljanz, including tuberculosis (TB), and other infections.
- Your doctor should test you for TB before starting Xeljanz and during treatment if necessary.

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- You may be at a higher risk of developing shingles (herpes zoster).
- People taking the higher dose (10 mg twice daily) of Xeljanz have a higher risk of serious infections and shingles.

Cancer

- Xeljanz may increase your risk of certain cancers by changing the way your immune system works.
- Lymphoma and other cancers including skin cancers (Non-Melanoma Skin Cancers) can happen in patients taking Xeljanz.
- People taking the higher dose (10 mg twice daily) of Xeljanz have a higher risk of skin cancers.

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- Tell your doctor if you have ever had any type of cancer.
- Periodic skin examination is recommended.

Tell your doctor immediately if you:

- Develop symptoms of an infection, such as fever, sweating, or chills, muscle aches, cough, shortness of breath, blood in phlegm, weight loss, red, or painful "skin", sores on your body, diarrhea, stomach pain, burning when you urinate or urinating more often than normal, feeling very tired.

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