version 2.1

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- Experience acute changes to your eyesight (blurry vision, partial or complete loss of vision), as this may be a sign of blood clots in the eyes.
- 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.

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 Haemoglobin**. This may mean that you have anemia, which may make you feel weak and tired. hemoglobin should be monitored at baseline and after 4-8 weeks of treatment and every 3 months thereafter.
- Lipids should be tested after 8 weeks following initiation of therapy
- Certain liver tests should be routinely tested.
- You should not receive Xeljanz if your lymphocyte count, neutrophil count,

or Haemoglobin is too low or your liver tests are too high.

- Periodic skin examination is recommended.
- 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 reporting portal which is available on the home page of the Ministry of Health website:
www.health.gov.il

or by this link:
https://sideeffects.health.gov.il

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

This card and its content have been approved by the Ministry of Health on December 2022

XELJANZ® Patient Safety Information Card

(Tofacitinib 5 mg,10 mg, XR 11mg)

The bearer of this card is treated with Xeljanz®

The Bearer of this card is treated with Xeljanz®

Patient's Name:

Date of Birth:

Address:

Doctor's Name:

Doctor's Phone:

Treatment (dose, times taken):

Indication / objective of treatment:

Date of treatment commencement:

This Patient Safety Information Card should be carried with you at all times. If you stop taking XELJANZ, keep this card with you for at least 2 months after taking the last dose of XELJANZ.

WHAT XELJANZ IS AND WHAT IT IS USED FOR

Xeljanz contains the active substance tofacitinib which works by blocking the action of enzymes known as Janus kinases.
Xeljanz XR 11 mg for the treatment of Rheumatoid arthritis
Xeljanz 5 mg for the treatment of Rheumatoid arthritis, Psoriatic arthritis, Ankylosing spondylitis and Ulcerative colitis.
Xeljanz 10 mg for induction treatment of Ulcerative colitis

For full information of the indications as approved by the Ministry of Health, see the consumer leaflet.

HOW TO TAKE XELJANZ

Recommended dose:

- for Rheumatoid arthritis: 5 mg twice daily or one extended-release tablet (11 mg) once daily

- for Psoriatic arthritis: 5 mg twice daily
- for Ankylosing spondylitis: 5 mg twice daily

Your doctor may decide to stop Xeljanz if Xeljanz does not work for you within 16 weeks.

- for Ulcerative colitis: 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 prescribed certain other medicines. In addition, treatment should be temporarily or permanently stopped if blood tests show low white blood cell or low haemoglobin.
- Tell your doctor if you have diabetes or are taking medicines to treat diabetes. Your doctor will decide whether to reduce the anti-diabetic medicine while you are taking XELJANZ. Notify your physician if you are taking or have recently taken medications containing antibiotics

(such as rifampicin, used to treat bacterial infections), fluconazole and ketoconazole (used to treat fungal infections), biologic DMARDs for rheumatoid arthritis or psoriatic arthritis, biologics for ulcerative colitis, other medicines that suppress your immune system (e.g. azathioprine, mercaptopurine, tacrolimus or ciclosporine) or any other medications, including OTC medications, vitamins and dietary or herbal supplements, or if you have liver or kidney problems and regarding any new medical condition.

- 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.

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 patient information leaflet.

Serious infections

- 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
- Your doctor should test you for TB before starting Xeljanz and during treatment.
- You may be at a higher risk of developing shingles (herpes zoster).

Cancer

- 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
- People taking the higher dose (10 mg twice daily) of Xeljanz have a higher risk of skin cancers.
- Tell your doctor if you have ever had any type of cancer, and also if you are a current or past smoke.

Cardiovascular events

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

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.