

TOFACITINIB TEVA Patient Safety Information Card

The Bearer of this card is treated with TOFACITINIB TEVA

Patient's Name: _____

Doctor's Name: _____

Doctor's Phone: _____

The date you started taking TOFACITINIB TEVA: _____

This card contains important safety information about TOFACITINIB TEVA.

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.

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

See the TOFACITINIB TEVA package leaflet for more information. You should use TOFACITINIB TEVA 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. Taking TOFACITINIB TEVA with certain medicines may increase your risk of side effects, immunosuppression, and infection.

The treatment with TOFACITINIB TEVA may increase the risk of infections and malignancies (including lung cancer, lymphoma, and non melanoma skin cancer).

Patients aged 65 years and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that TOFACITINIB TEVA is not suitable 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 TOFACITINIB TEVA, as these may be signs of a clot in the lungs or veins.
- You develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness.
- You develop any symptoms of herpes zoster, such as painful skin rash or blisters.

- You have been in close contact with a person with tuberculosis.
- You 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.
- You 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.
- You notice any new growth on the skin or any changes in existing moles or spots.
- You develop symptoms of interstitial lung disease, such as shortness of breath.
- You develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in your stool, or any change in your bowel habits with fever.
- You develop yellow skin, nausea or vomiting.
- You are due to receive any vaccine. You should not receive certain types of vaccines while taking TOFACITINIB TEVA.

Pregnancy and Lactation:

- Contact your doctor immediately if you become pregnant or plan on becoming pregnant.
- TOFACITINIB TEVA must not be used during pregnancy. Women of childbearing potential should be advised to use effective contraception during treatment with TOFACITINIB TEVA and for at least 4 weeks after the last dose.
- Women must not breast-feed while being treated with TOFACITINIB TEVA.

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 Teva Israel by email: safety.israel@teva.co.il

This card was approved according to the guidelines of the Ministry of Health on March 2025.