PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Tofacitinib Taro 5 mg

Tofacitinib Taro 10 mg

Film-Coated Tablets

Name and amount of active ingredient

Tofacitinib Taro 5 mg: Each tablet contains tofacitinib 5 mg

Tofacitinib Taro 10 mg: Each tablet contains tofacitinib 10 mg

Inactive ingredients and allergens in the preparation: See section 2 "Important information about some of the medicine's ingredients" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

In addition to this leaflet, Tofacitinib Taro also has a patient safety information card. This card contains important safety information that you need to know and that you should follow before starting and during treatment with Tofacitinib Taro. Read the patient safety information card and the patient leaflet before using this product. Keep the card for further reference if needed.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tofacitinib Taro is intended for:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Ulcerative colitis
- Active juvenile idiopathic arthritis and juvenile psoriatic arthritis

Therapeutic group: A Janus kinase (JAK) inhibitor

Rheumatoid arthritis

Tofacitinib Taro is used to treat adults with moderate to severe active rheumatoid arthritis, a long-term disease that mainly causes joint pain and swelling.

Tofacitinib Taro is used together with methotrexate when previous rheumatoid arthritis treatment was not sufficiently effective or was not tolerated. Tofacitinib Taro can also be used on its own in cases where methotrexate treatment is not tolerated or not recommended.

Treatment with Tofacitinib Taro has been shown to reduce joint pain and swelling and to improve the ability to perform daily activities when given on its own or together with methotrexate.

Psoriatic arthritis

Tofacitinib Taro is used to treat adults with psoriatic arthritis, an inflammatory disease of the joints, often accompanied by psoriasis. If you suffer from active psoriatic arthritis, you will initially be treated with another medicine. If you do not adequately respond to the medicine or if you do not tolerate it, you may be given Tofacitinib Taro to reduce the signs and symptoms of psoriatic arthritis and improve your ability to perform daily activities.

Tofacitinib Taro is used together with methotrexate to treat active psoriatic arthritis in adults.

Ankylosing spondylitis

Tofacitinib Taro is used to treat a condition called ankylosing spondylitis, an inflammatory disease of the spine.

If you suffer from ankylosing spondylitis, you may first be treated with other medicines. If you do not respond well enough to those medicines, you will be given Tofacitinib Taro. Tofacitinib Taro may help to reduce back pain and improve physical function, thus making daily activities easier and improving your quality of life.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel. Tofacitinib Taro is used in adult patients to reduce the signs and symptoms of ulcerative colitis when the response to previous treatment was inadequate or when the treatment was not tolerated.

Active juvenile idiopathic arthritis and juvenile psoriatic arthritis

Tofacitinib Taro is used to treat active juvenile idiopathic arthritis, a long-term disease that mainly causes joint pain and swelling in patients aged two years and over.

Tofacitinib Taro is also used to treat juvenile psoriatic arthritis, an inflammatory disease of the joints that is often accompanied by psoriasis, in patients aged two years and over.

Tofacitinib Taro may be used together with methotrexate if previous treatment of juvenile idiopathic arthritis or of juvenile psoriatic arthritis was inadequate or not well tolerated. Tofacitinib Taro can be taken on its own in cases where methotrexate treatment is not tolerated or not recommended.

2. BEFORE USING THIS MEDICINE

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6).
- If you are suffering from a severe infection, such as a bloodstream infection or active tuberculosis.
- If you have been told that you suffer from severe liver problems, including cirrhosis (scarring of the liver).
- If you are pregnant or breastfeeding.

If you are unsure about any of the above information, please contact your doctor.

Special warnings regarding use of the medicine

Before (and during) treatment with Tofacitinib Taro, tell your doctor if:

- You think you have an infection or experience **symptoms of an infection**, such as fever, sweating, chills, muscle pain, cough, shortness of breath, new phlegm or change in phlegm, weight loss, warm or red or painful skin or sores on your body, difficulty or pain swallowing, diarrhea or abdominal pain, a burning sensation when you urinate or increased frequency of urination, or feel very tired.
- You have **a condition that increases your chance of infection** (e.g., diabetes, HIV/AIDS, or a weak immune system).
- You have **any kind of infection**, are being treated for an infection, or have recurrent infections. You must inform your doctor immediately if you feel unwell. Tofacitinib Taro may reduce your body’s ability to respond to infections and cause an existing infection to get worse or increase the risk of a new infection.
- You have or have previously had **tuberculosis** or have been in close contact with someone who has tuberculosis. Your doctor will refer you for a tuberculosis test before treatment with Tofacitinib Taro, and possibly also during the course of treatment.

- You have any **chronic lung disease**.
- You have **liver problems**. See also “Do not use this medicine".
- You have or have previously had **hepatitis B or C** (viruses that affect the liver). The virus may become active during treatment with Tofacitinib Taro. Your doctor may refer you for blood tests for hepatitis before and during use of the medicine.
- **You are 65 or older**, have had **any type of cancer**, and also if you are a **current or past smoker**. Tofacitinib Taro may increase your risk of certain types of cancer. White blood cell cancer, lung cancer, and other types of cancer (e.g., breast, skin, prostate, and pancreatic) have been reported in patients treated with Tofacitinib Taro. If you develop cancer during treatment with Tofacitinib Taro, your doctor will assess whether you should stop treatment with the medicine.
- You are **at known risk of fractures**, e.g., if you are aged 65 or over, if you are a woman, or if you take corticosteroids (e.g., prednisone).
- Cases of **non-melanoma skin cancer** have been observed in patients taking Tofacitinib Taro. Your doctor may recommend that you have regular skin examinations while being treated with Tofacitinib Taro. If new skin lesions appear during or after treatment or if a change occurs in the appearance of existing lesions, tell your doctor.
- You have had **diverticulitis** (inflammation of the large intestine), or **ulcers of the stomach or intestine** (see section 4).
- You have **kidney problems**.
- You are **planning to get vaccinated**; inform your doctor. There are certain types of vaccines that you must not receive during treatment with Tofacitinib Taro. Before beginning treatment with Tofacitinib Taro, you should receive all recommended vaccinations. Your doctor will decide whether you should be vaccinated against shingles (herpes zoster).
- You have **heart problems, high blood pressure, high cholesterol, and also if you are a current or past smoker.**

There have been reports of patients treated with Tofacitinib Taro who developed **blood clots** in the lungs or veins. Your doctor will assess your risk for developing blood clots in the lungs or veins, and determine whether Tofacitinib Taro is suitable for you. If you have already had problems with blood clots developing in the lungs or veins, or if you are at increased risk for this (e.g., if you suffer from severe obesity, if you have cancer, heart problems, diabetes, have experienced a heart attack (in the past 3 months), have recently had major surgery, if you use hormonal contraception / hormone replacement therapy, if you or your close relatives have been found to have a coagulation defect), if you are of older age, or

are a current or past smoker, your doctor may decide that Tofacitinib Taro is not suitable for you.

Consult your doctor immediately if:

- While taking Tofacitinib Taro you develop **sudden shortness of breath or breathing difficulties, chest or upper back pain, swelling of your leg or arm, leg pain or tenderness, or redness or discoloration of your leg or arm**, as these could be signs of a blood clot in the lungs or veins.
- You notice **sudden changes in your vision** (blurred vision, partial or complete vision loss), as this could be a sign of a blood clot in your eyes.
- You, your partner or your caregiver notice **new onset of severe headaches**, which can be accompanied by nausea and vomiting, **fainting, dizziness or light-headedness, temporary vision problems, weakness on one side of the body, progressive decline in mental status, seizures, or loss of consciousness**, as these may be a sign of blood clots in veins around the brain.
- You develop **signs and symptoms of a heart attack**, including intense pain or pressure in your chest (which could spread to your arms, jaw, neck or back), shortness of breath, cold sweat, light-headedness, or sudden dizziness.

  There have been reports of patients treated with Tofacitinib Taro who suffered from heart problems, including heart attack. Your doctor will assess your risk for developing heart problems and will determine whether Tofacitinib Taro is suitable for you.
- You, your partner, or your caregiver notice the appearance or worsening of neurological symptoms, including general muscle weakness, vision disturbance, changes in thinking, memory, or orientation causing confusion and personality changes. Contact your doctor immediately, as these could be symptoms of a severe and very rare brain infection called progressive multifocal leukoencephalopathy (PML).

Tests and follow-up

Your doctor will refer you for a tuberculosis test before starting treatment with Tofacitinib Taro, and possibly also during the treatment. Your doctor may refer you for blood tests for hepatitis before and during treatment with this medicine.

Your doctor may recommend that you have regular skin examinations while being treated with Tofacitinib Taro, since cases of non-melanoma skin cancer have been observed in patients treated with Tofacitinib Taro. If new skin lesions appear during or after treatment or if a change occurs in the appearance of existing lesions, tell your doctor.

Your doctor will need to refer you for blood tests before you start treatment with Tofacitinib Taro, after 4-8 weeks of treatment, and then every 3 months, to

determine whether you have a low white blood cell (neutrophil or lymphocyte) count or a low red blood cell count (anemia).

Tofacitinib Taro should not be taken if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may stop your treatment with Tofacitinib Taro in order to reduce the risk of infection (white blood cell count) or anemia (red blood cell count).

Your doctor may also perform additional tests, such as testing for blood cholesterol levels or monitoring the health of your liver. Your doctor needs to check cholesterol levels 8 weeks after you begin treatment with Tofacitinib Taro. Your doctor needs to refer you for liver tests from time to time.

Elderly

There is a higher rate of infections, some of which may be serious, in patients aged 65 years and older. Contact your doctor as soon as you notice any signs or symptoms of infections.

Patients aged 65 and over may be at increased risk for infections, heart attack, and some types of cancer. Your doctor may decide that Tofacitinib Taro is not suitable for you.

Asian patients

There is a higher rate of shingles in Japanese and Korean patients. Tell your doctor if you notice any painful blisters on your skin.

You may also be at higher risk of certain lung problems. Contact your doctor if you notice breathing difficulties**.**

Smoking

If you are a current or past smoker, your doctor may decide that Tofacitinib Taro is not suitable for you.

Children and adolescents

The safety and benefits of Tofacitinib Taro in children under the age of two years have not been established.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. Especially in the following cases:

Tell your doctor if you have **diabetes** or if you **take medicines to treat diabetes**. Your doctor will decide whether to reduce the dose of the diabetes medications while you are taking Tofacitinib Taro.

Some medicines **should not be taken with Tofacitinib Taro**. These medicines, if taken with Tofacitinib Taro, could alter the level of Tofacitinib Taro in the body, and might necessitate adjusting the dosage of Tofacitinib Taro. You must inform your doctor if you are using medicines containing any of the following active ingredients:

- Antibiotics such as rifampicin, used to treat bacterial infections
- Fluconazole, ketoconazole, used to treat fungal infections

It is not recommended to take Tofacitinib Taro together with medicines that suppress the immune system, including medicines called targeted biological therapies (antibodies), such as TNF inhibitors, interleukin-17 inhibitors, interleukin-12/ interleukin-23 inhibitors, anti-integrins, and strong chemical immunosuppressants, including azathioprine, mercaptopurine, ciclosporin, and tacrolimus. Taking Tofacitinib Taro in combination with these medicines could increase the risk of side effects, including infections.

Severe infections and fractures may occur more frequently in people who are also taking corticosteroids (e.g., prednisone).

Use of the medicine and food

Can be taken with or without a meal.

Pregnancy, breastfeeding, and fertility

If you are a woman of childbearing age, you must use an effective contraception during treatment with Tofacitinib Taro, and for at least 4 weeks after your last dose.

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with your doctor before taking the medicine. Tofacitinib Taro must not be used during pregnancy. Tell your doctor immediately if you become pregnant during treatment with Tofacitinib Taro.

Do not use Tofacitinib Taro while breastfeeding. If you are taking Tofacitinib Taro and breastfeeding, you must stop breastfeeding until you consult with your doctor about stopping treatment with Tofacitinib Taro.

Driving and operating machinery

Tofacitinib Taro has no or negligible effect on the ability to drive or use machines.

Important information about some of the medicine's ingredients

The medicine contains lactose monohydrate. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult your doctor before starting treatment with this medicine.

The medicine contains sodium. This medicine contains less than 1 millimole sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

Rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis

The recommended dose is one 5 mg tablet taken twice a day.

Ankylosing spondylitis

Your doctor may decide to stop treatment with Tofacitinib Taro if it does not help you within 16 weeks.

Ulcerative colitis

- The recommended dose is 10 mg twice a day for 8 weeks, and then 5 mg twice a day.
- Your doctor may decide to extend the initial treatment of 10 mg twice a day by an additional 8 weeks (total of 16 weeks), followed by 5 mg twice a day.
- Your doctor may decide to stop treatment with Tofacitinib Taro if it is not effective for you within 16 weeks of treatment.
- For patients who have previously taken biological medicines to treat ulcerative colitis (such as TNF inhibitors) and these medicines did not work, your doctor may decide to increase your Tofacitinib Taro dosage to 10 mg twice daily if you do not respond well enough to 5 mg twice daily. Your doctor will assess the possible risks, including the development of blood clots in your lungs or veins, and the possible benefits for you. Your doctor will tell you if this applies to you.
- If your treatment is interrupted, your doctor may decide to restart the treatment.

Use in children and adolescents

Juvenile idiopathic arthritis and juvenile psoriatic arthritis

The recommended dosage is 5 mg twice a day for patients weighing 40 kg and over.

Do not exceed the recommended dose.

How to take:

Take one tablet in the morning and one tablet in the evening. Try to take the tablets at the same time every day.

The tablet may be crushed and taken with water.

Your doctor may reduce your dose if you suffer from liver or kidney problems or if you take certain other medicines.

Your doctor may also stop your treatment, temporarily or permanently, if blood tests show low white blood cell or red blood cell counts.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, contact a doctor immediately or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the dose at the regular time and continue as normal.

Adhere to the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Tofacitinib Taro may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Some of the side effects may be serious and may require medical attention.

Side effects in children and adolescents with juvenile idiopathic arthritis and juvenile psoriatic arthritis were similar to those observed in adults with rheumatoid arthritis, with the exception of certain infections (influenza, pharyngitis, sinusitis, viral infection) and gastrointestinal or general disorders (abdominal pain, nausea, vomiting, fever, headache, cough), which were more common in the juvenile idiopathic arthritis population.

Possible severe side effects (see the section “Special warnings regarding use of the medicine”)

In rare cases, life-threatening infection may occur.
Additionally, lung cancer, white blood cell cancer, and heart attack have been reported.

If you notice any of the following serious side effects, inform your doctor immediately

Signs of serious infections (common) include:

- Fever and chills
- Cough
- Skin blisters
- Abdominal pain
- Persistent headaches

Signs of ulcers or perforations (holes) in your stomach (uncommon) include:

- Fever
- Abdominal or stomach pain
- Blood in the stool
- Unexplained changes in bowel movements

Holes in the stomach or intestines mostly occur in people who are also taking nonsteroidal anti-inflammatory drugs or corticosteroids (such as prednisone).

Signs of allergic reactions (frequency unknown) include:

- Chest tightness
- Wheezing
- Severe dizziness or light-headedness
- Swelling of the lips, tongue, or throat
- Hives (itching or skin rash)

Signs of blood clots in the lungs, veins, or eyes (uncommon: venous thromboembolism) include:

- Sudden shortness of breath or breathing difficulties
- Chest or upper back pain
- Swelling of the leg or arm
- Leg pain or tenderness
- Leg or arm redness or discoloration
- Sudden changes in vision
- New onset of severe headaches
- Fainting, dizziness or light-headedness
- Weakness on one side of the body, progressive decline in mental status, seizures, or loss of consciousness

Signs of a heart attack (uncommon) include:

- Severe chest pain or tightness (which could spread to the arms, jaw, neck, back)
- Shortness of breath
- Cold sweat
- Light-headedness or sudden dizziness

Additional side effects

Common side effects (may affect up to 1 in 10 people): lung infection (pneumonia and bronchitis), shingles (herpes zoster), infections of the nose, throat, or windpipe (nasopharyngitis), influenza, sinusitis, inflammation of the urinary bladder (cystitis), sore throat (pharyngitis), elevated muscle enzymes in the blood (sign of muscle problems), abdominal pain (which may be caused by inflammation of the stomach lining), vomiting, diarrhea, nausea, indigestion, low white blood cell count, low red blood cell count (anemia), swelling of the feet and hands, headaches, high blood pressure (hypertension), cough, rash, acne.

Uncommon side effects (may affect up to 1 in 100 people): lung cancer, tuberculosis, kidney infection, skin infection, herpes simplex or cold sores (herpes of the lips), elevated blood creatinine level (a possible sign of kidney problems), elevated cholesterol level (including elevated LDL), fever, fatigue, weight gain, dehydration, muscle strain, tendonitis, joint swelling, joint sprain, abnormal sensations, poor sleep, sinus congestion, shortness of breath or breathing difficulties, skin redness, itching, fatty liver, painful inflammation of small pouches in the lining of your intestine (diverticulitis), viral infections, viral infections affecting the gut, some types of skin cancers (non-melanoma).

Rare side effects (may affect up to 1 in 1,000 people): blood infection (sepsis), lymphoma (white blood cell cancer), disseminated tuberculosis involving bones and other organs, other unusual infections, joint infections, elevated levels of liver enzymes in the blood (sign of liver problems), and muscle and joint pain.

Very rare side effects (may affect up to 1 in 10,000 people): tuberculosis involving the brain and spinal cord, meningitis, inflammation of the soft tissue and fascia.

In general, fewer side effects were observed when Tofacitinib Taro was used alone than in combination with methotrexate in the treatment of rheumatoid arthritis.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the homepage of the Ministry of

Health (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Tofacitinib Taro 5 mg:

Microcrystalline cellulose, lactose monohydrate, Opadry® complete film coating system 03G58632 white (hypromellose, titanium dioxide, macrogol, triacetin), croscarmellose sodium, magnesium stearate.

Tofacitinib Taro 10 mg:

Microcrystalline cellulose, lactose monohydrate, Opadry® II film coating system 33G505016 blue (hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin, FD&C blue#2, FD&C blue #1), croscarmellose sodium, magnesium stearate.

What the medicine looks like and contents of the package:

Tofacitinib Taro 5 mg:

A round, white, film-coated tablet, with the word "RX 13" imprinted on one side and plain on the other side.

Tofacitinib Taro 10 mg:

A round, blue, film-coated tablet, with the word "RX 21" imprinted on one side and plain on the other side.

The product is marketed in a package containing 60 film-coated tablets in a blister pack, or in a bottle containing 28, 60 or 180 film-coated tablets.

Not all pack sizes may be marketed.

Registration holder and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

Manufacturer's name and address:

SUN Pharmaceutical Industries Ltd.
SUN HOUSE; Plot No. 201 B/1, Western Express Highway, Goregaon (E)
Mumbai 400063, Maharashtra, India.

Revised in May 2026.

numbers of the medicine in the Ministry of Health's National Drug Registry:

Tofacitinib Taro 5 mg: 178-47-37690-99

Tofacitinib Taro 10 mg: 178-48-37691-99

For further information about this medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code

Tofacitinib Taro 5 mg

Tofacitinib Taro 10 mg

https://israeldrugs.health.gov.il/#!/medDetails/178%2047%2037690%2099
https://israeldrugs.health.gov.il/#!/medDetails/178%2048%2037691%2099

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info.taro@sunpharma.com or by phone 1-800-464-664.

The bearer of this card is treated with Tofacitinib Taro

Patient's name:

Doctor's name:

Doctor's phone number:

Date of starting treatment with Tofacitinib Taro:

This card contains important safety information about Tofacitinib Taro.

If this information is not clear to you, please ask your doctor or pharmacist to explain it to you. Keep this card and present it to any doctor or pharmacist involved in your care.

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

Read the patient information leaflet for more information. You should use Tofacitinib Taro according to 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 nutritional supplements. Taking Tofacitinib Taro with certain medicines may increase your risk of side effects, immunosuppression and infections.

The treatment with Tofacitinib Taro 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 high risk of infections, heart attack and certain types of cancer. Your doctor may decide that Tofacitinib Taro is not suitable for you.

Contact your doctor **immediately** if you:

- Develop sudden shortness of breath or breathing difficulties, chest or upper back pain, swelling of the leg or arm, leg pain or tenderness, or leg or arm redness or color change while taking Tofacitinib Taro, as these may be signs of a clot in the lungs or veins.
- Develop symptoms of infection, such as fever, persistent cough, weight loss, or excessive tiredness.
- Develop symptoms of herpes zoster, such as blisters or painful rash on the skin.
- Have been in close contact with a person with tuberculosis.
- Develop intense pain or pressure in your chest (which could spread to your arms, jaw, neck and back), shortness of breath, cold sweat, a sensation

that you are about to faint or sudden dizziness, as these may be signs of a heart attack.
- Develop swelling of lymph nodes in your neck, armpits or groin, constantly feeling tired, develop fever, night sweats, experience persistent or worsening cough, develop breathing difficulties, hoarseness or wheezing, or unexplained weight loss.
- Notice any new lesion 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 accompanied by fever.
- Develop yellow skin, nausea or vomiting.
- Are planning to receive any vaccine. There are certain types of vaccines that you must not receive during treatment with Tofacitinib Taro.
- Become pregnant or plan to become pregnant.

Tofacitinib Taro must not be used during pregnancy. Women of childbearing age should use effective contraception methods during treatment with Tofacitinib Taro and for at least 4 weeks after the last dose.

Do not breastfeed during treatment with Tofacitinib Taro.

Reporting side effects

Side effects can be reported to the Ministry of Health by the portal for reporting side effects found on the homepage of the Ministry of Health: www.health.gov.il, or by entering the link: https://sideeffects.health.gov.il

Side effects can also be reported to Taro by email: drug.safety@sunpharma.com

This card was approved according to the guidelines of the Ministry of Health in April 2025.

Safety Information Card

for a patient treated with Tofacitinib Taro

(Tofacitinib 5 mg, 10 mg)