

# TARO-TOFACITINIB XR PATIENT SAFETY INFORMATION



**SUN**  
PHARMA

## How This Medicine Works

TARO-TOFACITINIB XR is a medicine that reduces the immune response in your body by interfering with the activity of an enzyme called janus kinase (JAK) that normally helps to activate the immune response. It is used to reduce the signs and symptoms of rheumatoid arthritis when other treatments do not work. To ensure your safety while taking TARO-TOFACITINIB XR, please review the information in this card carefully.

## How to take TARO-TOFACITINIB XR

- Always take TARO-TOFACITINIB XR exactly as your healthcare professional tells you.
- TARO-TOFACITINIB XR can be taken with or without food.
- Your doctor may reduce the dose if you have liver or kidney problems. You should not increase the dose.
- TARO-TOFACITINIB XR should not be used if you have or develop a serious infection until the infection is controlled.

Your healthcare professional may prescribe TARO-TOFACITINIB XR alone or in combination with other medication(s). If you receive treatment with another drug, your healthcare professional will tell you how to take it. Be sure to read the package leaflets for the other drugs as well as this one.

### Usual Dose:

The following is the recommended dose of TARO-TOFACITINIB XR depending on your medical condition. Your doctor may adjust your dose based on your kidney or liver function, or other considerations. It is important that you do not increase your own dose of TARO-TOFACITINIB XR.

If you have rheumatoid arthritis (RA):

- The recommended dose of TARO-TOFACITINIB XR is 11 mg, taken by mouth once daily.
- Swallow TARO-TOFACITINIB XR tablets whole. Do NOT crush, split or chew the tablets.
- TARO-TOFACITINIB XR, monotherapy may be considered in cases of intolerance to methotrexate and to one or more DMARDs.

### Overdose:

If you think, or a person you are caring for, have taken too much TARO-TOFACITINIB XR, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

### Missed Dose:

If you have missed your dose of TARO-TOFACITINIB XR, take the next dose as planned at the next scheduled time. Do NOT take a double dose to make up for a forgotten dose.

## Serious Warnings and Precautions

### Serious Infections

- You should NOT take TARO-TOFACITINIB XR if you have an active infection.
- TARO-TOFACITINIB XR is a medicine that affects your immune system. It can lower the ability of your body to fight infections such as tuberculosis, shingles (herpes zoster) and infections caused by other bacteria, fungi, or viruses that can spread throughout the body.
- In some cases, these infections may lead to hospitalization or death.
- Most patients who developed infections were taking other medicines, such as methotrexate or corticosteroids at the same time. These medicines make it harder to fight infections.
- Your healthcare professional will closely monitor you for the signs and symptoms of infections during and after the treatment with TARO-TOFACITINIB XR.
- Contact your healthcare professional if you have any signs or symptoms of an infection, such as:
  - fever, sweating, or chills,
  - muscle aches,
  - cough, shortness of breath,
  - blood in spit,
  - weight loss,
  - warm, red, or painful skin or sores on your body,
  - diarrhea or stomach pain,
  - burning when you urinate or urinating more often than normal,
  - feeling very tired;
- If a serious infection develops, stop taking TARO-TOFACITINIB XR and contact your healthcare professional right away.

### Cancers and immune conditions

- Lymphoma, lung cancer, and other cancers have been reported in patients treated with TARO-TOFACITINIB.
- Your healthcare professional will closely monitor you for signs and symptoms of cancer and other serious conditions during treatment with TARO-TOFACITINIB.

### Blood clots

- Blood clots in the veins of your legs or arms (deep vein thrombosis, DVT), arteries (arterial thrombosis) or lungs (pulmonary embolism, PE) can happen in some people taking TARO-TOFACITINIB XR. This may be life-threatening and cause death.
- Stop taking TARO-TOFACITINIB XR and seek medical help right away if you develop any signs or symptoms of:
  - Blood clots in your leg (such as swelling, pain or tenderness).

### Major heart problems

- Major heart problems have been reported in Rheumatoid Arthritis patients treated with TARO-TOFACITINIB XR.
- Talk to your healthcare professional about possible heart disease risk factors before you start taking TARO-TOFACITINIB XR.
- If you develop signs and symptoms of a heart problem, stop taking TARO-TOFACITINIB XR and contact your healthcare professional right away. Symptoms may include:
  - new or worsening chest pain,
  - shortness of breath,
  - irregular heartbeats,
  - swelling of the legs.

## Do not use TARO-TOFACITINIB XR if:

- you are allergic to tofacitinib or any other non-medicinal ingredients in TARO-TOFACITINIB XR.
- you are pregnant or are planning to become pregnant.
- you are breast-feeding or intend to breast-feed. Talk to your healthcare professional about the best way to feed your baby while taking TARO-TOFACITINIB XR.
- you have severe liver problems.

## To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TARO-TOFACITINIB XR. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection, get a lot of infections or have infections that keep coming back;
- have diabetes, HIV/AIDS, or a weak immune system. People with these conditions have a higher chance for infections;
- have tuberculosis, or a history of tuberculosis or have been in close contact with someone with tuberculosis;
- have or have had hepatitis B or C;
- have known narrowing or blockage of your digestive tract (intestines or another part of your bowel are not as wide as normal). This is important if you will be taking TARO-TOFACITINIB XR or if you are switching from TARO-TOFACITINIB to TARO-TOFACITINIB XR;
- have gastrointestinal problems, including gastrointestinal perforations (tear in the stomach or intestines), diverticulitis (inflammation in parts of the large intestine), ulcers in your stomach or intestines;
- have low blood counts. Treatment with TARO-TOFACITINIB XR can be associated with low red blood cell counts (anemia), or with low white blood cell counts (neutrophils or lymphocytes);
- have high cholesterol;
- have or have had any type of cancer;
- have liver problems;
- have kidney problems;
- have a history of interstitial lung disease (diseases that inflame or scar lung tissue);
- have muscle pain or muscle weakness;
- develop new skin lesions during or after therapy or if existing lesions change appearance;
- have received any vaccines (shots) within 1 month prior to starting TARO-TOFACITINIB XR or are planning to get vaccinated. Certain types of vaccines (shots) should not be given when taking TARO-TOFACITINIB XR. Before you start TARO-TOFACITINIB XR, you should be up to date with all recommended vaccinations, including a shingles vaccine;
- have had blood clots in your legs (deep vein thrombosis), eyes (retinal venous thrombosis) or lungs (pulmonary embolism) or have been told you are at risk of blood clots;
- have problems with your blood clotting (thrombophilia);
- have chest pain, heart failure or any heart problems, or heart disease risk factors, such as if you:
  - are a current or past smoker,
  - have high blood pressure (hypertension),
  - have diabetes,
  - have a family history of premature coronary heart disease,
  - have had coronary artery disease. This is when blood vessels that supply your heart are clogged;
- have other diseases associated with rheumatoid arthritis, such as: lumps (nodules), anemia, lung problems, a type of immune problem called Sjögren's syndrome;
- are of Asian descent. You may be at increased risk of serious side effects.
- have risk factors for broken bones, such as if you: are older than 65 years of age, are a woman, or take a type of medicine called corticosteroids.

## Other warnings you should know about:

### Blood tests and monitoring

You may need blood tests before you start TARO-TOFACITINIB XR. These tests may be repeated while you are taking TARO-TOFACITINIB XR. Your healthcare professional will also monitor your liver tests and blood cholesterol levels 4 to 8 weeks after you start receiving TARO-TOFACITINIB XR and routinely thereafter. These will help your healthcare professional find out how TARO-TOFACITINIB XR is affecting your blood and how well your liver is working.

Your healthcare provider will check the following when you start taking tofacitinib:

- White and red blood cell counts
- Cholesterol levels
- Kidney function (creatinine level in the blood)
- Liver function (liver enzyme levels known as transaminases in the blood)

### Female patients

Pregnancy and birth control

- Avoid becoming pregnant while taking TARO-TOFACITINIB XR. It may harm your unborn baby.
- If you are of child-bearing age, use an effective method of birth control while taking TARO-TOFACITINIB XR. Continue using birth control for 4 to 6 weeks after you stop taking TARO-TOFACITINIB XR.

### Adults aged 65 years and older

- Side effects, including serious side effects, have occurred more often in patients aged 65 years and older.

## Interactions

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with TARO-TOFACITINIB XR:**

- other medicines used to treat rheumatoid arthritis, psoriatic arthritis or ulcerative colitis, including:
  - Biologics such as: abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab, secukinumab, ustekimumab, vedolizumab.
  - Other JAK inhibitors such as: baricitinib and upadacitinib.
- medicines that affect your immune system (such as azathioprine, 6-mercaptopurine, tacrolimus, sirolimus, cyclosporine)
- antiarrhythmics (medicines used to treat heart rhythm problems)
- beta-blockers (medicines used to slow the heart or lower blood pressure), and calcium channel blockers (medicines used to lower blood pressure)
- cholinesterase inhibitors (medicines used to treat Alzheimer's)
- HIV protease inhibitors
- a medicine used to treat bacterial infections like tuberculosis called rifampin, and medicines for fungal infections (such as ketoconazole, fluconazole)
- grapefruit juice
- St. John's Wort (an herbal medicine also known as hypericum perforatum). It may reduce the response to TARO-TOFACITINIB XR.

## Side Effects

### What are possible side effects from using TARO-TOFACITINIB XR?

These are not all the possible side effects you may have when taking TARO-TOFACITINIB XR. If you experience any side effects not listed here, tell your healthcare professional.

The side effects of TARO-TOFACITINIB XR include:

- Upper respiratory tract infection (such as a cold),
- Nasopharyngitis (nose or throat infection, runny or stuffy nose), Cough
- Headache, dizziness
- Diarrhea, vomiting, nausea (feeling queasy, feeling like you may throw up)
- Indigestion (heartburn or upset stomach)
- Back pain, joint pain
- Rash
- Muscle weakness/pain

### If any of the above affects you severely, tell your healthcare professional.

TARO-TOFACITINIB XR may cause abnormal blood test results, including changes in cholesterol levels, white or red blood cell counts or creatinine levels (a protein that may increase in people with kidney problems). Your healthcare professional will decide when to perform blood tests and will interpret the results.

## When to Seek Medical Attention

**It is important to talk with your healthcare professional if you experience any of the following when taking TARO-TOFACITINIB XR:**

### Common

- Broken bones
- Cellulitis (skin infection with redness, swelling, and pain)
- Gastritis: stomach ache, loss of appetite
- Hypertension (high blood pressure): measured high blood pressure, sometimes with headache or nosebleed
- Pneumonia (infection with coughing, fever, fatigue)
- Urinary tract infections: difficulty or increased need to urinate; pain or burning sensation when passing urine, pain in pelvis or mid-back, urine that appears cloudy

### Uncommon

- Anemia/neutropenia/lymphopenia (low blood cell counts): fatigue, loss of energy, weakness, shortness of breath
- Bronchitis: persistent cough, fatigue, shortness of breath
- Flu: cough, sore throat, feverish chills
- Severe increased creatine kinase levels: muscle weakness and/or muscle pain
- Kidney problems: change in the amount, frequency or colour (pale or dark) of urine
- Peripheral edema: swelling of legs and ankles or the arms and hands
- Skin cancer: lesions during or after therapy or if existing lesions change appearance

**Stop taking TARO-TOFACITINIB XR and get immediate medical help if you experience any of the following:**

**Common**

- Herpes Zoster (shingles): skin rash or blisters usually on one side of the body with itching, burning, or tingling pain
- Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat

**Uncommon**

- Allergic reaction: hives, rash, swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing
- Congestive heart failure: shortness of breath when you exert yourself or lie down, swelling in your legs, ankles and feet, irregular heartbeat, persistent cough
- Deep vein thrombosis (blood clot in the leg): swelling, pain or tenderness in the leg
- Retinal venous thrombosis (blood clot in the eyes): blurry vision, partial or complete loss of vision.
- Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, throwing up, loss of appetite with itching
- Lung cancer: Worsening cough, shortness of breath, chest pain, loss of appetite, coughing up blood, fatigue, unexplained weight loss

- Lymphoma (cancer of the lymphatic system): painless swelling of lymph node, swollen tonsils, fever, chills, night sweats, feeling tired, itching, unexplained weight loss, loss of appetite, persistent coughing/difficulty breathing or not being able to breathe, and headache
- Pulmonary embolism (blood clot in the lung): sharp chest pain, coughing up blood, sudden shortness of breath

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*



---

**REACHING PEOPLE. TOUCHING LIVES.**

1.800.268.1975 | [www.SunPharma.com](http://www.SunPharma.com)

© 2025 Sun Pharma, or its subsidiaries or affiliates. All rights reserved.  
All trademarks are the property of their respective owners.