Auro-Tofacitinib

AUROPHARMA
Your Trusted Partner In Generics

A Generic Bioequivalent to Xeljanz®

Auro-Tofacitinib is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) with an inadequate response, loss of response or intolerance to either conventional UC therapy or a TNF inhibitor.

Empowering Healthcare through: AuroCare+

A Patient Support Program aimed to ensure your continued treatment

The medical information contained in this material is provided for educational purposes only and is not intended to replace discussions with a healthcare professional.

Any decision regarding patient care must be made with a healthcare professional.

AuroCare+

More about Auro Care and how to get enrolled to our PSP program

1-866-845-4354

1-833-876-5930

AuroCare@supportprogram.com

Hours of operation: Monday to Friday 8 AM to 8 PM

Know your condition

- **Rheumatoid Arthritis:** Rheumatoid arthritis is a chronic inflammatory disorder that can affect more than just your joints. In some people, the condition can damage a wide variety of body systems, including the skin, eyes, lungs, heart and blood vessels. An autoimmune disorder, rheumatoid arthritis occurs when your immune system mistakenly attacks your own body's tissues.

- **Psoriatic Arthritis:** Psoriatic arthritis is a form of arthritis that affects some people who have psoriasis-a disease that causes red patches of skin topped with silvery scales. Most people develop psoriasis years before being diagnosed with psoriatic arthritis. But for some, the joint problems begin before skin patches appear or at the same time.

- **Ulcerative Colitis:** Ulcerative colitis is an inflammatory bowel disease (IBD) that causes inflammation and ulcers (sores) in digestive tract. Ulcerative colitis affects the innermost lining of large intestine, also called the colon, and rectum. In most people, symptoms usually develop over time, rather than suddenly.

Causes and Risk Factors

Rheumatoid Arthritis is an autoimmune disease. It’s not well known what start this disease although a genetic component appears likely.

Risk Factors

Gender: Women are more likely than men to develop rheumatoid arthritis.

Family history: If a member of your family has rheumatoid arthritis, you may have an increased risk of the disease.

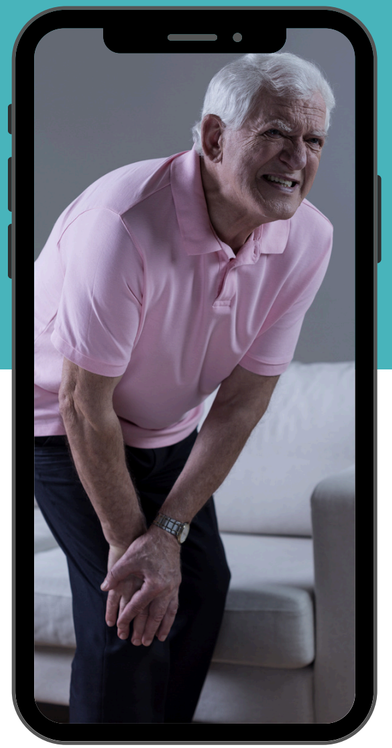
Excess weight: People who are overweight appear to be at a somewhat higher risk of developing rheumatoid arthritis

Age: Rheumatoid arthritis can occur at any age, but it most commonly begins in middle age.

Smoking: Cigarette smoking increases your risk of developing rheumatoid arthritis, particularly if you have genetic predisposition for developing the disease.

AuroCare+

Psoriatic Arthritis: Psoriatic arthritis occurs when your body's immune system attacks healthy cells and tissue. The immune response causes inflammation in your joints as well as overproduction of skin cell



Risk Factors

Psoriasis: Having psoriasis is the single greatest risk factor for developing psoriatic arthritis

Family history: Many people with psoriatic arthritis have a parent or a sibling with the disease.

Age: Although anyone can develop psoriatic arthritis, it occurs most often in adults between the ages of 30 and 55.

Ulcerative Colitis: The exact cause of ulcerative colitis remains unknown. One possible cause is an immune system malfunction. When your immune system tries to fight off an invading virus or bacterium, an irregular immune response causes the immune system to attack the cells in the digestive tract, too.

Risk Factors

Age: Ulcerative colitis usually begins before the age of 30, but it can occur at any age. Some people may not develop the disease until after age 60.

Race or ethnicity: Although white people have the highest risk of the disease, it can occur in any race. If you're of Ashkenazi Jewish descent, your risk is even higher.

Family history: You're at higher risk if you have a close relative, such as a parent, sibling or child, with the disease.

Signs and Symptoms associated with Condition

Rheumatoid Arthritis: Early rheumatoid arthritis tends to affect your smaller joints first-particularly the joints that attach your fingers to hands and your toes to your feet. As the disease progresses, symptoms often spread to the wrists, knees, ankles, elbows, hips and shoulders. In most cases, symptoms occur in the same joints on both sides of your body.

- Tender, warm, swollen joints
- Joint stiffness that is usually worse in the mornings and after inactivity
- Fatigue, fever and loss of appetite

Psoriatic arthritis: Psoriatic arthritis can affect joints on one or both sides of body. The signs and symptoms of psoriatic arthritis often resemble those of rheumatoid arthritis. Both diseases cause joints to become painful, swollen and warm to the touch

- Swollen fingers and toes
- Foot pain
- Lower back pain
- Nail changes
- Eye inflammation

Ulcerative Colitis: Ulcerative colitis symptoms can vary, depending on the severity of inflammation and where it occurs

- Diarrhea, often with blood or pus
- Rectal Pain & bleeding — passing small amount of blood with stool
- Abdominal pain and cramping
- Urgency to defecate
- Inability to defecate despite urgency
- Weight loss
- Fatigue
- Fever

Auro-Tofacitinib - How it works?

Tofacitinib, is a type of drug known as a Janus kinase (JAK) inhibitor. It works by blocking the action of Janus kinase enzymes (JAK1, JAK2, JAK3, and to a lesser extent TyK2), which are involved in the inflammation that causes the symptoms of rheumatoid arthritis and psoriatic arthritis.

Tofacitinib is a long-term treatment. Most people who benefit from this treatment will notice an improvement in the first 12 weeks of starting treatment.

Auro-Tofacitnib

How?
What?
Why?

What if I miss a dose?

If a patient missed a dose of Auro-Tofacitinib, they should continue with the next tablet at the usual time. Patients should not take a double dose to make up for a missed dose.

How will Auro-Tofacitinib be taken?

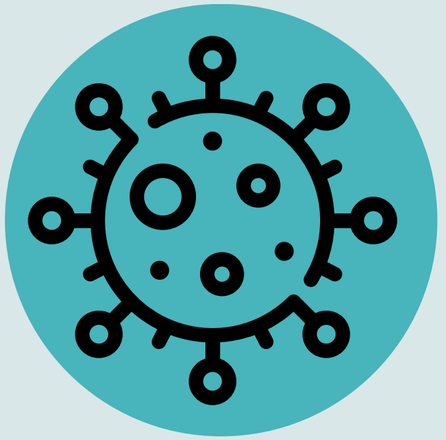
Auro-Tofacitinib is to be taken orally with or without food.

Important Patient Safety Information

- Before and after starting Tofacitinib, tell your doctor if you are being treated for an infection, have infections that keep coming back, or have symptoms of an infection. Patients treated with Auro-Tofacitinib (tofacitinib) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Auro-Tofacitinib until the infection is controlled.

- **Cancer:** Lymphoma and other malignancies have been observed in patients treated with tofacitinib. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with tofacitinib and concomitant immunosuppressive medications. An increase in malignancies, including lung cancer, were observed in rheumatoid arthritis patients 50 years or older with at least one additional cardiovascular (CV) risk factor who were taking tofacitinib compared with TNF inhibitors. Caution should be applied when using Auro-Tofacitinib in geriatric patients, patients who are current or past smokers, and patients with other malignancy risk factors.

- **Major Adverse Cardiovascular Events:** Major adverse cardiovascular events, including non-fatal myocardial infarction, were observed more frequently with tofacitinib compared to TNF inhibitors in rheumatoid arthritis patients who were 50 years or older with at least one additional CV risk factor.

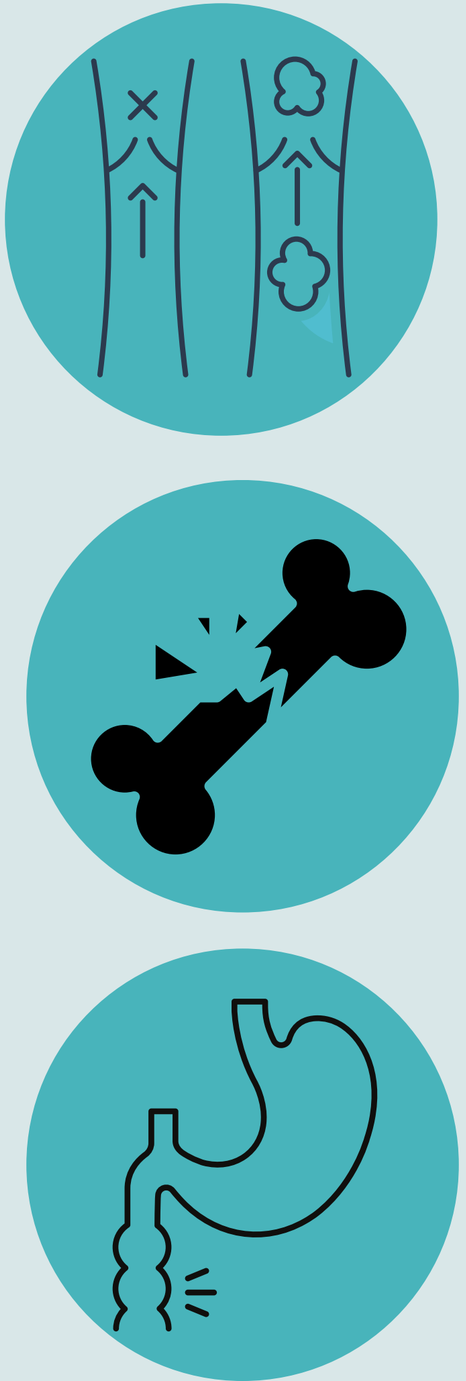


Important Patient Safety Information

- **Thrombosis:** Rheumatoid arthritis patients with at least one CV risk factor had a higher rate of all-cause mortality and thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis, with tofacitinib 10 mg twice daily (BID) compared to those treated with 5 mg BID or TNF blockers. Many of these adverse events were serious and some resulted in death. Avoid Auro-Tofacitinib in patients at risk of thrombosis.

- **Fractures:** Fractures of multiple types, including osteoporotic fractures, have been observed in patients treated with tofacitinib in clinical studies and the post marketing setting.

- **Gastrointestinal Perforation/Tears:** Events of gastrointestinal perforation have been reported with tofacitinib in RA patients, in clinical trials and in the post-market setting. Auro-Tofacitinib should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., use of concomitant NSAIDs and/or corticosteroids, patients with a history of diverticulitis). Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation.



Changes in certain lab investigation results

- Treatment with tofacitinib has been associated with decreases in hemoglobin levels. Evaluate hemoglobin prior to initiation of Auro-Tofacitinib.

- Treatment with tofacitinib was associated with initial lymphocytosis at one month of exposure followed by a gradual decrease in mean lymphocyte counts below the baseline of approximately 10% during 12 months of therapy. Lymphocyte counts less than 0.5 x 109 cells/L were associated with an increased incidence of treated and serious infections.

- Treatment with tofacitinib was associated with an increased incidence of neutropenia (<2 x 109 cells/L). Evaluate neutrophil count prior to initiation of Auro-Tofacitinib approximately 4-8 weeks after initiation with Auro-Tofacitinib treatment, and every 3 months thereafter.

- Treatment with tofacitinib was associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol.

- Auro-Tofacitinib is contraindicated in patients with severe hepatic impairment. Treatment with tofacitinib was associated with an increased incidence of liver enzyme elevation.

AuroCare+

Lab Result

AuroCare+

Contraindications

Auro-Tofacitinib (tofacitinib citrate) is contraindicated:

- In patients with known hypersensitivity to tofacitinib or ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- In patients with severe hepatic impairment
- During pregnancy and breastfeeding

REPORTING ADVERSE EVENTS

If you get any side effects and are worried about them, talk to your doctor, pharmacist or nurse. This includes any possible side effects which are not listed in the Auro-Tofacitinib package leaflet. You can report any suspected side effects associated with the use of health products to Health Canada OR Aurocare PSP by:

Health Canada / Santé Canada

1. **Call**
   1-866-234-2345
2. **Visit URL**
   https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

AuroCare+

1. **Call**
   1-866-845-4354
2. **Fax**
   1-833-876-5930
3. **Email**
   AuroCare@supportprogram.com

Hours of operation: Monday to Friday 8 AM to 8 PM

Ask your doctor about other potential side effects. Tell your doctor about any side effect that bothers you or does not go away.