

MEDICATION GUIDE

Tofacitinib (toe" fa sye" ti nib) Tablets, for oral use

What is the most important information I should know about tofacitinib tablets?

Tofacitinib tablets may cause serious side effects including:

1. Serious infections. Tofacitinib tablets are medicines that affect your immune system. Tofacitinib tablets can lower the ability of your immune system to fight infections. Some people can have serious infections while taking tofacitinib tablets, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting tofacitinib tablets and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with tofacitinib tablets.

You should not start taking tofacitinib tablets if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).

People with ulcerative colitis taking the higher dose of tofacitinib tablets (10 mg twice daily) have a higher risk of serious infections and shingles. Before starting tofacitinib tablets, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
 - o fever, sweating, or chills
 - o muscle aches
 - o cough
 - o shortness of breath
 - o blood in phlegm
 - o weight loss
 - o warm, red, or painful skin
 - o diarrhea or stomach pain
 - o sores on your body
 - o feeling very tired
 - o burning when you urinate
 - o feeling very tired or urinating more often than normal
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you take tofacitinib tablets. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B or C.

After starting tofacitinib tablets, call your healthcare provider right away if you have any symptoms of an infection. Tofacitinib tablets can make you more likely to get infections or make worse any infection that you have.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking tofacitinib tablets 5 mg or 10 mg twice daily.

3. Cancer and immune system problems. Tofacitinib tablets may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers including skin cancers can happen in people taking tofacitinib tablets. People taking tofacitinib tablets 5 mg twice daily or tofacitinib tablets 10 mg twice daily have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker. People with ulcerative colitis taking the higher dose of tofacitinib tablets (10 mg twice daily) have a higher risk of skin cancers. Tell your healthcare provider if you have ever had any type of cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking tofacitinib tablets 5 mg or 10 mg twice daily, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking tofacitinib tablets, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. Blood clots in the lungs, veins of the legs or arms, and arteries. Blood clots in the lungs (pulmonary embolism, PE), veins of the legs (deep vein thrombosis, DVT) and arteries (arterial thrombosis) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking tofacitinib tablets 5 mg or 10 mg twice daily. Blood clots in the lungs have also happened in people with ulcerative colitis. Some people have died from these blood clots.

- Stop taking tofacitinib tablets and tell your healthcare provider right away if you develop signs and symptoms of a blood clot, such as sudden shortness of breath or difficulty breathing, chest pain, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm.

6. Tears (perforation) in the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking tofacitinib tablets can get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

7. Allergic reactions.

- Symptoms such as swelling of your lips, tongue, or throat, or hives (raised, red patches of skin that are often very itchy) that may mean you are having an allergic reaction have been seen in people taking tofacitinib tablets. Some of these reactions were serious. If any of these symptoms occur while you are taking tofacitinib tablets, stop tofacitinib tablets and call your healthcare provider right away.

8. Changes in certain laboratory test results.

Your healthcare provider should do blood tests before you start taking tofacitinib tablets and while you take tofacitinib tablets to check for the following side effects:

- **changes in lymphocyte counts.** Lymphocytes are white blood cells that help the body fight off infections.
- **low neutrophil counts.** Neutrophils are white blood cells that help the body fight off infections.
- **low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired.

Your healthcare provider should routinely check certain liver tests.

You should not take tofacitinib tablets if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high.

Your healthcare provider may stop your tofacitinib tablets treatment for a period of time if needed because of changes in these blood test results.

You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start taking tofacitinib tablets, and as needed after that. Normal cholesterol levels are important to good heart health.

See **"What are the possible side effects of tofacitinib tablets?"** for more information about side effects.

What are tofacitinib tablets?

- Tofacitinib tablets are a prescription medicine called a Janus kinase (JAK) inhibitor. Tofacitinib tablets are used to treat adults with moderately to severely active rheumatoid arthritis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used and did not work well or cannot be tolerated.
- Tofacitinib tablets are used to treat adults and children 2 years of age and older with active psoriatic arthritis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.
- Tofacitinib tablets are used to treat adults with active ankylosing spondylitis when 1 or more TNF blocker medicines have been used and did not work well or cannot be tolerated.
- Tofacitinib tablets are used to treat adults with moderately to severely active ulcerative colitis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.
- Tofacitinib tablets are used to treat children 2 years of age and older with active polyarticular course juvenile arthritis when 1 or more TNF blocker medicines have been used, and did not work well or cannot be tolerated.

It is not known if tofacitinib tablets are safe and effective in people with Hepatitis B or C.

Tofacitinib tablets are not recommended for people with severe liver problems.

It is not known if tofacitinib tablets are safe and effective in children for treatment other than active polyarticular course juvenile arthritis and psoriatic arthritis.

What should I tell my healthcare provider before taking tofacitinib tablets? Before taking tofacitinib tablets, tell your healthcare provider

about all of your medical conditions, including if you:

- have an infection. See **“What is the most important information I should know about tofacitinib tablets?”**
- are a current or past smoker.
- have had any type of cancer.
- have had a heart attack, other heart problems or stroke.
- have had blood clots in the veins of your legs, arms, or lungs, or clots in the arteries in the past.
- have liver problems.
- have kidney problems.
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have had a reaction to tofacitinib or any of the ingredients in tofacitinib tablets.
- have recently received or are scheduled to receive a vaccine. People who take tofacitinib tablets should not receive live vaccines. People taking tofacitinib tablets can receive non-live vaccines.
- plan to become pregnant or are pregnant. Tofacitinib tablets may affect the ability of females to get pregnant. It is not known if this will change after stopping tofacitinib tablets. It is not known if tofacitinib tablets will harm an unborn baby.
- plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take tofacitinib tablets or breastfeed. You should not do both. After you stop your treatment with tofacitinib tablets do not start breastfeeding again until:
 - o 18 hours after your last dose of tofacitinib tablets

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tofacitinib tablets and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- any other medicines to treat your rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis or polyarticular course juvenile arthritis. You should not take tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), infliximab (Remicade), rituximab (Rituxan), abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), ustekinumab (Stelara), secukinumab (Cosentyx), vedolizumab (Entyvio), ixekizumab (Taltz), azathioprine, cyclosporine, or other immunosuppressive drugs while you are taking tofacitinib tablets. Taking tofacitinib tablets with these medicines may increase your risk of infection.
 - medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take tofacitinib tablets?

Take tofacitinib tablets exactly as your healthcare provider tells you to take it.

- Take tofacitinib tablets 2 times a day with or without food.
- If you take too much tofacitinib tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- For the treatment of psoriatic arthritis, take tofacitinib tablets in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.

What are the possible side effects of tofacitinib tablets?

Tofacitinib tablets may cause serious side effects, including:

- See **“What is the most important information I should know about tofacitinib tablets?”**
- **Hepatitis B or C activation infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while you use tofacitinib tablets. Your healthcare provider may do blood tests before you start treatment with tofacitinib tablets and while you are taking tofacitinib tablets. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B or C infection:
 - o feel very tired
 - o little or no appetite
 - o clay-colored bowel movements
 - o chills
 - o muscle aches
 - o skin rash
 - o skin or eyes look yellow
 - o vomiting
 - o fevers
 - o stomach discomfort
 - o dark urine

Common side effects of tofacitinib tablets in people with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- diarrhea
- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- high blood pressure (hypertension)
- acne

Common side effects of tofacitinib tablets in people with ulcerative colitis include:

- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- increased cholesterol levels
- headache
- upper respiratory tract infections (common cold, sinus infections)
- increased muscle enzyme levels
- rash
- acne
- diarrhea
- shingles (herpes zoster)

Common side effects of tofacitinib tablets in children with polyarticular course juvenile arthritis and psoriatic arthritis include:

- upper respiratory tract infections (common cold, sinus infections)
- nasal congestion, sore throat, and runny nose (nasopharyngitis)
- headache
- fever
- nausea
- vomiting
- acne

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of tofacitinib tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Macleods Pharma USA, Inc., at 1-888-943-3210 or 1-855-926-3384.

How should I store tofacitinib tablets?

- Store tofacitinib tablets at 20°C -25°C (68°F-77°F); excursions permitted to 15°C to 30°C (59°F-86°F) [see USP Controlled Room Temperature]. Protect from exposure to high humidity.

Keep tofacitinib tablets and all medicines out of the reach of children.

General information about the safe and effective use of tofacitinib tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tofacitinib tablets for a condition for which it was not prescribed. Do not give tofacitinib tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about tofacitinib tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about tofacitinib tablets that is written for health professionals.

What are the ingredients in tofacitinib tablets 5 mg?

Active ingredient: tofacitinib citrate

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, HPMC 2910/Hypromellose 6 mPas, titanium dioxide, macrogol/PEG MW 3350, triacetin.

What are the ingredients in tofacitinib tablets 10 mg?

Active ingredient: tofacitinib citrate

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, HPMC 2910/Hypromellose 15 mPas, titanium dioxide, Macrogol/PEG MW 4000, Triacetin, FD&C BLUE #2, FD&C BLUE #1



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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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