Tofacitinib

Generic name: tofacitinib
Brand names: Xeljanz, Xeljanz XR
Dosage form: oral tablet, oral extended-release tablet, oral solution
Drug class: Antirheumatics

Medically reviewed by Philip Thornton, DipPharm. Last updated on Aug 23, 2023.

What is tofacitinib?

Tofacitinib is a prescription medication called a janus kinase (JAK) inhibitor. It is a disease modifying anti-rheumatic drug (DMARD), which works by suppressing the immune system. Tofacitinib is available in the form of a tablet (Xeljanz), an extended release tablet (Xeljanz XR) and as an oral solution.

It is used to treat certain inflammatory conditions in people who have already tried tumor necrosis factor (TNF) blockers.

When tofacitinib was approved by the FDA in 2012, it was the first approved JAK inhibitor for the treatment of rheumatoid arthritis and also the first new oral DMARD to be approved for the condition in more than a decade.

What is tofacitinib used for?

- Tofacitinib tablets and tofacitinib XR are used to treat adults with moderately to severely active rheumatoid arthritis when 1 or more medicines called TNF blockers have been used and did not work well or cannot be tolerated.
- Tofacitinib tablets and tofacitinib XR are used to treat adults 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 and tofacitinib XR 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 and tofacitinib XR 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 and oral solution is used to treat people 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 and tofacitinib XR are safe and effective in people with Hepatitis B or C.

Tofacitinib is not recommended for people with severe liver problems.

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

It is not known if tofacitinib XR is safe and effective in children.

Important information

Tofacitinib may cause serious side effects including:

1. Serious infections.

Tofacitinib is a medicine that affects your immune system. Tofacitinib can lower the ability of your immune system to fight infections. Some people can have serious infections while taking tofacitinib, 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 and during treatment.
- Your healthcare provider should monitor you closely for signs and symptoms of TB infection during treatment with tofacitinib.

You should not start taking tofacitinib 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 (10 mg twice daily) or tofacitinib XR (22 mg one time each day) have a higher risk of serious infections and shingles.

Before starting tofacitinib, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
    - fever, sweating, or chills
    - cough
    - blood in phlegm
    - warm, red, or painful skin or sores on your body
    - burning when you urinate or urinating more often than normal
    - muscle aches
    - shortness of breath
    - weight loss
    - diarrhea or stomach pain
    - feeling very tired
- 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. 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, call your healthcare provider right away if you have any symptoms of an infection. tofacitinib 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 5 mg twice daily or tofacitinib 10 mg twice daily.

3. Cancer and immune system problems.

Tofacitinib 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. People taking tofacitinib 5 mg twice daily or tofacitinib 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 (10 mg twice daily) or tofacitinib XR (22 mg one time each day) have a higher risk of skin cancers. Tell your healthcare provider if you have ever had any type of cancer.
- Some people who have taken tofacitinib with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr Virus-associated post-transplant lymphoproliferative disorder).

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 5 mg twice daily or tofacitinib 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, 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 5 mg twice daily or tofacitinib 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 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 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 and tofacitinib XR. Some of these reactions were serious. If any of these symptoms occur while you are taking tofacitinib, stop tofacitinib 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 and while you take tofacitinib 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 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 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, and as needed after that. Normal cholesterol levels are important to good heart health.

See "What are the side effect of tofacitinib?" below for more information about side effects.

What should I tell my doctor before taking tofacitinib?

Before taking tofacitinib, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection. See "Important information" above.
- 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.
- have recently received or are scheduled to receive a vaccine. People who take tofacitinib should not receive live vaccines. People taking tofacitinib can receive non-live vaccines.

Tofacitinib pregnancy and breastfeeding warnings (more detail)

How should I take tofacitinib?

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

- Take tofacitinib tablets and oral solution 2 times a day with or without food.
- Take tofacitinib XR 1 time a day with or without food.
- Swallow tofacitinib XR whole and intact. Do not crush, split, or chew.
- When you take tofacitinib XR, you may see something in your stool that looks like a tablet. This is the empty shell from the tablet after the medicine has been absorbed by your body.
- For the treatment of psoriatic arthritis, take tofacitinib tablets and tofacitinib XR in combination with methotrexate, sulfasalazine or leflunomide as instructed by your healthcare provider.
- Tofacitinib XR should not be used instead of tofacitinib oral solution.

What happens if I overdose?

If you take too much tofacitinib, call your healthcare provider or go to the nearest hospital emergency room right away.

Dosing information

Administration Instructions

- Tofacitinib XR not interchangeable or substitutable with tofacitinib oral solution.
- Changes between tofacitinib tablets and tofacitinib XR should be made by the healthcare provider.
- Do not initiate tofacitinib if absolute lymphocyte count <500 cells/mm3, an absolute neutrophil count (ANC) <1000 cells/mm3 or hemoglobin <9 g/dL. (2.1)

Recommended Dosage

- Rheumatoid Arthritis
  - Tofacitinib 5 mg twice daily or tofacitinib XR11 mg once daily.
  - Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is tofacitinib 5 mg once daily.

- Psoriatic Arthritis (in combination with nonbiologic DMARDs)
  - Tofacitinib 5 mg twice daily or tofacitinib XR 11 mg once daily.
  - Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is tofacitinib 5 mg once daily.
- Ankylosing Spondylitis
  - tofacitinib 5 mg twice daily or tofacitinib XR 11 mg once daily.
  - Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is tofacitinib 5 mg once daily.
- Ulcerative Colitis
  - Induction: Tofacitinib 10 mg twice daily or tofacitinib XR 22 mg once daily for 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue tofacitinib 10 mg twice daily or tofacitinib XR 22 mg once daily for a maximum of 16 weeks. Discontinue tofacitinib 10 mg twice daily or tofacitinib XR 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved.
  - Maintenance: tofacitinib 5 mg twice daily or tofacitinib XR 11 mg once daily. For patients with loss of response during maintenance treatment, tofacitinib 10 mg twice daily or tofacitinib. XR 22 mg once daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.
  - Dosage adjustment is needed in patients with moderate and severe renal impairment or moderate hepatic impairment: see full prescribing information.
- Polyarticular Course Juvenile Idiopathic Arthritis
  - Tofacitinib tablets or tofacitinib oral solution 5 mg twice daily or weight-based equivalent twice daily.
  - Dosage adjustment is needed in patients with moderate and severe renal impairment or moderate hepatic impairment: see full prescribing information.

Detailed Tofacitinib dosage information

What are the side effects of tofacitinib?

Tofacitinib may cause serious side effects, including:

- See "Important information" above.
- 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. Your healthcare provider may do blood tests before you start treatment with tofacitinib and while you are taking tofacitinib. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B or C infection:
  - feel very tired
  - little or no appetite
  - clay-colored bowel movements
  - chills
  - muscle aches

- skin rash
- skin or eyes look yellow
- vomiting
- fevers
- stomach discomfort
- dark urine

Common side effects of tofacitinib tablets and tofacitinib XR 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)

Common side effects of tofacitinib tablets and tofacitinib XR 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
- diarrhea
- shingles (herpes zoster)

Common side effects of tofacitinib tablets and tofacitinib oral solution in people with polyarticular course juvenile arthritis include:

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

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. 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 Pfizer at 1-800-438-1985.

Tofacitinib side effects (more detail)

Related/similar drugs

Rinvoq

Rinvoq (upadacitinib) is used to treat rheumatoid arthritis, psoriatic arthritis, atopic ...

Reviews & ratings

7.0 / 10

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Xeljanz

Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor that may be used alone or with other ...

Reviews & ratings

5.7 / 10

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Entyvio

Entyvio (vedolizumab) is used to treat ulcerative colitis (UC) and Crohn's disease, reducing ...

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6.2 / 10

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Otezla

Otezla (apremilast) is used to treat plaque psoriasis, psoriatic arthritis, and oral ulcers ...

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5.2 / 10

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Skyrizi

Skyrizi (risankizumab) is used to treat plaque psoriasis, psoriatic arthritis, ulcerative colitis ...

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Omvoh

Omvoh is used to treat moderate to severe ulcerative colitis or Crohn's disease in adults. This ...

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Stelara

Stelara (ustekinumab) is used to treat Crohn's disease, ulcerative colitis, plaque psoriasis, and ...

Reviews & ratings

7.6 / 10

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Celecoxib

Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) used to treat pain or inflammation ...

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Hydroxychloroquine

Hydroxychloroquine is a quinoline drug used to treat or prevent malaria. It's also used to treat ...

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6.4 / 10

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Dexamethasone

Dexamethasone is used to treat inflammatory conditions such as allergies, skin conditions ...

Reviews & ratings

5.9 / 10

162 Reviews

View more

Interactions

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tofacitinib 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. Taking tofacitinib 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.

Tofacitinib drug interactions (more detail)

Does tofacitinib interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

tofacitinib

+

Enter a drug name Add

Pregnancy and breastfeeding

Tell your doctor if you plan to become pregnant or are pregnant. Tofacitinib may affect the ability of females to get pregnant. It is not known if this will change after stopping tofacitinib. It is not known if tofacitinib will harm an unborn baby.

- Pregnancy Registry: Pfizer has a registry for pregnant women who take tofacitinib. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking tofacitinib, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

Tell your doctor if you plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take tofacitinib or breastfeed. You should not do both. After you stop your treatment with tofacitinib do not start breastfeeding again until:

- 18 hours after your last dose of tofacitinib tablets or oral solution or
- 36 hours after your last dose of tofacitinib XR

Storage

- Store tofacitinib tablets and tofacitinib XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Store tofacitinib oral solution at room temperature between 68°F to 77°F (20°C to 25°C) in the original bottle and carton to protect from light.
- Safely throw away tofacitinib oral solution that is out of date or no longer needed. Use tofacitinib oral solution within 60 days of opening the bottle. Throw away (discard) remaining oral solution after 60 days.

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

What are the ingredients in tofacitinib?

Active ingredient: tofacitinib citrate

Inactive ingredients:

Tofacitinib 5mg tablets: croscarmellose sodium, HPMC 2910/Hypromellose 6cP, lactose monohydrate, macrogol/PEG3350, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin.

Tofacitinib 10mg tablets: croscarmellose sodium, FD&C Blue #1/Brilliant Blue FCF Aluminum Lake, FD&C Blue #2/Indigo Carmine Aluminum Lake, HPMC 2910/Hypromellose 6cP, lactose monohydrate, macrogol/PEG3350, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin.

Tofacitinib XR 11mg: cellulose acetate, copovidone, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/Hypromellose, magnesium stearate, red iron oxide, sorbitol, titanium dioxide, and triacetin. Printing ink contains ammonium hydroxide, ferrosoferric oxide/black iron, propylene glycol, and shellac glaze.

Tofacitinib 5mg tablets 22mg: cellulose acetate, copovidone, FD&C Blue #2 Aluminum Lake, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/Hypromellose, magnesium stearate, red iron oxide, sorbitol, titanium dioxide, triacetin, and yellow iron oxide. Printing ink contains ammonium hydroxide, ferrosoferric oxide/black iron oxide, propylene glycol, and shellac glaze.

Tofacitinib oral solution: grape flavor (natural), hydrochloric acid, lactic acid, purified water, sodium benzoate, sucralose, and xylitol.

Tofacitinib is distributed by Pfizer Labs, Division of Pfizer Inc, NY, NY 10017.

Popular FAQ

Is Xeljanz an immunosuppressant?

Who makes Xeljanz and where is it made?

More FAQ

- What are the new drugs for rheumatoid arthritis (RA)?

References

1. National Library of Medicine Xeljanz Product Label

More about tofacitinib

- Check interactions
- Compare alternatives
- Reviews (172)
- Latest FDA alerts (4)
- Side effects
- Dosage information
- During pregnancy
- Drug class: antirheumatics
- Breastfeeding
- En español

Patient resources

Other brands

Xeljanz

Professional resources

- Tofacitinib monograph

Other brands

Xeljanz

Related treatment guides

- Ankylosing Spondylitis
- Psoriatic Arthritis
- Ulcerative Colitis
- Polyarticular Juvenile Idiopathic Arthritis
- Rheumatoid Arthritis

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability
Rx Prescription only

Pregnancy & Lactation
Risk data available

CSA Schedule*
N/A Not a controlled drug

Approval History
Drug history at FDA

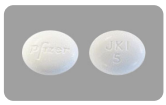
User Reviews & Ratings

5.7 / 10

172 Reviews

Images

Xeljanz (tofacitinib) 5 mg (Pfizer JKI 5)



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