

[Home](#) → [Drugs, Herbs and Supplements](#) → Tofacitinib

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URL of this page: <https://medlineplus.gov/druginfo/meds/a613025.html>

## Tofacitinib

pronounced as (toe" fa sye' ti nib)

### IMPORTANT WARNING:

Taking tofacitinib may decrease your ability to fight infection and increase the risk that you will get a serious infection, including severe fungal, bacterial, or viral infections that spread through the body. These infections may need to be treated in a hospital and may cause death. Tell your doctor if you often get any type of infection or if you think you may have any type of infection now. This includes minor infections (such as open cuts or sores), infections that come and go (such as cold sores), and chronic infections that do not go away. Also tell your doctor if you have or have ever had diabetes, human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), a lung disease, or any other condition that affects your immune system. You should also tell your doctor if you live or have ever lived in areas such as the Ohio or Mississippi river valleys where severe fungal infections are more common. Ask your doctor if you are not sure if these infections are common in your area. Tell your doctor if you are taking medications that decrease the activity of the immune system such as the following: abatacept (Orencia); adalimumab (Humira); anakinra (Kineret); azathioprine (Azasan); certolizumab (Cimzia); cyclosporine (Gengraf, Neoral, Sandimmune); etanercept (Enbrel); golimumab (Simponi); infliximab (Remicade); methotrexate (Otrexup, Rasuvo, Trexall); rituximab (Rituxan); steroids including dexamethasone, methylprednisolone (Medrol), prednisolone (Orapred ODT, Prelone), and prednisone (Rayos); tacrolimus (Astagraf, Envarsus XR, Prograf); and tocilizumab (Actemra).

Your doctor will monitor you for signs of infection during and after your treatment. If you have any of the following symptoms before you begin your treatment or if you experience any of the following symptoms during or shortly after your treatment, call your doctor immediately: fever; sweating; chills; muscle aches; painful or difficult swallowing; cough; shortness of breath; weight loss; warm, red, or painful skin; painful rash; headache, sensitivity to light, neck stiffness, confusion; frequent, painful, or burning feeling during urination; stomach pain; diarrhea; or excessive tiredness.

You may already be infected with tuberculosis (TB; a serious lung infection) but not have any symptoms of the disease. In this case, using tofacitinib may make your infection more serious and cause you to develop symptoms. Your doctor will perform a skin test to see if you have an inactive TB infection before you begin your treatment with tofacitinib. If necessary, your doctor will give you medication to treat this infection before you start using tofacitinib. Tell your doctor if you have or

have ever had TB, if you have lived in or visited a country where TB is common, or if you have been around someone who has TB. If you have any of the following symptoms of TB, or if you develop any of these symptoms during your treatment, call your doctor immediately: cough, coughing up bloody mucus, weight loss, loss of muscle tone, or fever.

Taking tofacitinib may cause serious or life-threatening heart problems, such as a heart attack or stroke, or serious or life-threatening blood clots in the legs, arms, lungs, or in the arteries during your treatment. Tell your doctor if you smoke or if you have ever smoked. Also tell your doctor if you have or have ever had a heart attack or other heart problems; a stroke; a blood clot in your legs, arms, or lungs, or in the arteries; high cholesterol; high blood pressure; or diabetes. If you experience any of the following symptoms during your treatment, call your doctor immediately or get emergency medical treatment: pain in the chest, arms, back, neck, jaw, or stomach; breaking out in cold sweat; feeling light-headed; dizziness; numbness or weakness in face, arm, or legs; slow or difficult speech; sudden shortness of breath or difficulty breathing; swelling of a leg or arm; leg pain; redness, discoloration, or warmth in the legs or arms.

Taking tofacitinib may increase the risk that you will develop a lymphoma (cancer that begins in the blood cells that fight infection) or other types of cancers, including lung cancer and skin cancer. Some people who took tofacitinib with other medications after they had a kidney transplant developed a condition that caused their bodies to produce too many white blood cells. Tell your doctor if you have or have ever had any type of cancer or have had a kidney transplant. Also tell your doctor if you smoke or if you have ever smoked.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with tofacitinib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

## Why is this medication prescribed?

Tofacitinib is used alone or with other medications to treat rheumatoid arthritis (condition in which the body attacks its own joints causing pain, swelling, and loss of function) in adults who are unable to take or did not respond to one or more tumor necrosis factor (TNF) inhibitor medication(s). It is also used to treat psoriatic arthritis (a condition that causes joint pain and swelling and scales on the skin) in adults who are unable to take or did not respond to or tolerate one or more TNF inhibitor medication(s). Tofacitinib is used to treat ulcerative colitis (a condition which causes swelling and sores in the lining of the colon [large intestine] and rectum) in adults who are unable to take or who did not respond to one or more TNF inhibitor medication(s). It is also used to treat polyarticular juvenile idiopathic arthritis (PJIA; a type of childhood arthritis that affects five or more joints during the first six months of the condition, causing pain, swelling, and loss of function) in children 2 years and older who are unable to take or who

did not respond to one or more TNF inhibitor medication(s). Tofacitinib is in a class of medications called Janus kinase (JAK) inhibitors. It works by decreasing the activity of the immune system.

## How should this medicine be used?

Tofacitinib comes as a tablet, an extended-release (long-acting) tablet, and as an oral solution (liquid) to take by mouth. For the treatment of ulcerative colitis, rheumatoid arthritis, or psoriatic arthritis, the tablet is usually taken twice daily with or without food and the extended-release tablet is usually taken once daily with or without food. For the treatment of polyarticular course juvenile idiopathic arthritis, the tablet or the oral solution is usually taken twice daily with or without food. Take tofacitinib at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take tofacitinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release tablets whole; do not split, chew, or crush them.

Always use the oral dosing syringe that comes with tofacitinib solution to measure your dose. Talk to your doctor or pharmacist if you have questions about how to measure your dose of tofacitinib solution.

If you or your child are taking tofacitinib oral solution, ask your pharmacist or doctor for a copy of the manufacturer's instructions for use. Carefully read these instructions.

Your doctor may need to decrease your dose or stop your treatment if you experience certain severe side effects. Be sure to tell your doctor how you are feeling during your treatment.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking tofacitinib,

- tell your doctor and pharmacist if you are allergic to tofacitinib, any other medications, or any of the ingredients in tofacitinib tablets, extended release tablets, or oral solution. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: certain antifungal medications such as fluconazole (Diflucan), itraconazole (Sporanox, Tolsura), and ketoconazole; aspirin and other nonsteroidal anti-inflammatory medications (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Naprosyn, Aleve); carbamazepine (Carbatrol, Equetro, Tegretol, others); clarithromycin (Biaxin, in Prevpac); certain medications for HIV including indinavir (Crixivan), nelfinavir (Viracept), and ritonavir (Norvir, in Kaletra); nefazodone; phenobarbital; phenytoin (Dilantin, Phenytek); rifabutin (Mycobutin); and rifampin (Rifadin, Rimactane). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor what herbal products you are taking, especially St. John's wort.

- tell your doctor if you have stomach pain that has not been diagnosed and if you have or have ever had ulcers (sores in the lining of your stomach or intestine), diverticulitis (swelling of the lining of the large intestine), liver disease including hepatitis B or hepatitis C, cancer, anemia (a lower than normal number of red blood cells), dialysis (medical treatment to clean the blood when the kidneys are not working properly), or kidney disease. If you are taking the extended-release tablets, tell your doctor if you have a narrowing or blockage of your digestive system.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are taking tofacitinib. If you become pregnant while taking tofacitinib, call your doctor.
- tell your doctor if you are breastfeeding. Do not breastfeed while you are taking tofacitinib tablets or oral solution and for at least 18 hours after the final dose of the tablet or for at least 36 hours after the final dose of the extended-release tablet.
- you should know that this medication may decrease fertility in women. Talk to your doctor about the risks of taking tofacitinib.
- tell your doctor if you have recently received or are scheduled to receive any vaccinations. If you need any vaccinations, you may have to receive the vaccinations and then wait some time before beginning your treatment with tofacitinib. Do not have any vaccinations during your treatment without talking to your doctor.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Tofacitinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- diarrhea
- headache
- stuffy or runny nose

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:**

- hives, swelling of face, eyes, lips, or throat, difficulty swallowing or breathing
- stomach pain, especially if it comes along with fever and diarrhea or constipation
- yellowing of the skin or eyes
- loss of appetite
- dark urine

- clay-colored bowel movements
- vomiting
- rash
- pale skin
- shortness of breath

Tofacitinib may cause an increase in your blood cholesterol levels. Your doctor will order tests to monitor your cholesterol levels during your treatment with tofacitinib. Talk to your doctor about the risks of taking this medication.

Tofacitinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Discard any unused solution 60 days after opening the bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to tofacitinib.

If you are taking the extended-release tablets you may notice something that looks like a tablet in your bowel movement. This is just the empty tablet shell, and this does not mean that you did not get your full dose of medication.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Xeljanz<sup>®</sup>
- Xeljanz<sup>®</sup> XR

Last Revised - 02/15/2022

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Page last updated: 25 March 2022