



ELSEVIER

Tofacitinib Oral tablet, extended-release

U.S. Trade Names

Xeljanz XR

The list of names may not include all products that are available on the market.

This medicine can lower your body's ability to fight infections. You may get more infections while taking this medicine. Any infection you get could become serious and even deadly. Before you get this medicine, tell your healthcare provider if you get a lot of infections or have infections that keep coming back. Also tell them all the prescriptions you take. After you get this medicine, call your healthcare provider right away if you get an infection or have signs of infection like fever, cough, flu-like symptoms, or have open cuts or sores on your body. Risk factors for this condition include: getting a lot of infections or have infections that keep coming back, history of tuberculosis, taking medicine that makes your immune system weak, like methotrexate or corticosteroids. Report the following side effects to your healthcare provider immediately: blood in phlegm, burning when you urinate or urinate more often than normal, cough that does not go away, general ill feeling (extreme tiredness, weakness or aches), loss of body fat and muscle (wasting) or weight loss, low grade fever, stomach symptoms (nausea, vomiting, diarrhea or stomach pain), sweats or chills, symptoms of a cold (shortness of breath, cough, or sore throat), trouble breathing, like shortness of breath or wheezing, warm, red, or painful skin or sores on your body, white patches in your mouth or throat.

This medicine may increase the risk of death in some patients.

Taking this medicine can increase the risk of getting cancer. Risk factors for this condition include: history of cancer, or currently have cancer. Report the following side effects to your healthcare provider immediately: a bump or open sore on your skin that doesn't heal, fever that does not go away, bruising or bleeding very easily, or looking very pale, night sweats, stomach pain, swelling, or fullness, swollen glands in the neck, armpits, or groin, unexplained fever, unexplained weight loss, weakness or tiredness that does not go away.

This medicine can cause post-transplant lymphoproliferative disorder (PTLD). PTLD is when certain white blood cells grow out of control after a transplant. PTLD can go to the brain, and lead to cancer or death. People who were never exposed to Epstein-Barr virus (EBV) are at higher risk for PTLD. You should get a blood test for EBV before you get this medicine. Do not start treatment unless your test says you are EBV positive. Risk factors for this condition include: kidney transplant, taking other medicines that make your immune system weak.

This medicine increases the risk of blood clots. Report the following side effects to your healthcare provider immediately: chest pain, confusion, trouble speaking, or sudden trouble seeing, coughing up blood, pain in your leg(s), with or without swelling, sudden trouble walking, dizziness, loss of balance or coordination, swelling of an arm or leg, trouble breathing or shortness of breath.

What is this medicine?

TOFACITINIB (TOE fa SYE it nib) is a medicine that works on the immune system. This medicine is used to treat rheumatoid arthritis and psoriatic arthritis. It is also used to treat ulcerative colitis.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- cancer
- diabetes

- heart disease
- high blood pressure
- high cholesterol
- history of blood clots
- HIV or AIDS
- immune system problems
- infection (especially a virus infection such as hepatitis B, chickenpox, cold sores, or herpes)
- kidney disease
- liver disease
- low blood counts, like low white cell, platelet, or red cell counts
- lung or breathing disease, like asthma
- organ transplant
- stomach or intestine problems
- tuberculosis, a positive skin test for tuberculosis, or have recently been in close contact with someone who has tuberculosis
- an unusual or allergic reaction to tofacitinib, other medicines, foods, dyes, or preservatives
- pregnant or trying to get pregnant
- breast-feeding

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Swallow the tablet whole. Do not cut, crush or chew this medicine. You can take it with or without food. If it upsets your stomach, take it with food. Take your medicine at regular intervals. Do not take it more often than directed. Do not stop taking except on your doctor's advice.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once. NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What may interact with this medicine?

- antiviral medicines for hepatitis, HIV or AIDS
- azathioprine
- biologic medicines such as abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, ofatumumab, rituximab, sarilumab, secukinumab, tocilizumab, ustekinumab, vedolizumab

- certain medicines for fungal infections like fluconazole, itraconazole, ketoconazole, voriconazole
- certain medicines for seizures like carbamazepine, phenobarbital, phenytoin
- cyclosporine
- live vaccines
- medicines that lower your chance of fighting infection
- rifampin
- supplements, such as St. John's wort
- tacrolimus

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- breathing problems
- dizziness
- signs and symptoms of a blood clot such as chest pain; shortness of breath; pain, swelling, or warmth in the leg
- signs of infection like fever; chills; cough; sore throat; pain or trouble passing urine
- signs and symptoms of liver injury like dark yellow or brown urine; general ill feeling or flu-like symptoms; light-colored stools; loss of appetite; nausea; right upper belly pain; unusually weak or tired; yellowing of the eyes or skin
- signs and symptoms of low red blood cells or anemia such as unusually weak or tired; feeling faint or lightheaded; falls; breathing problems
- stomach pain or a sudden change in bowel habits

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- diarrhea
- headache
- muscle aches
- runny nose
- sinus trouble

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Visit your healthcare professional for regular checks on your progress. Tell your healthcare professional if your symptoms do not start to get better or if they get worse. You may need blood work done while you are taking this medicine.

The tablet shell of this medicine does not dissolve. This is normal. The tablet shell may appear whole in the stool. This is not a cause for concern.

Avoid taking products that contain aspirin, acetaminophen, ibuprofen, naproxen, or ketoprofen unless instructed by your doctor. These medicines may hide a fever.

Call your doctor or health care professional for advice if you get a fever, chills or sore throat, or other symptoms of a cold or flu. Do not treat yourself. This drug decreases your body's ability to fight infections. Try to avoid being around people who are sick.

Women should inform their doctor if they wish to become pregnant or think they might be pregnant. There is a potential for serious side effects to an unborn child. Talk to your health care professional or pharmacist for more information.

Do not breast-feed an infant while taking this medicine or for at least 36 hours after stopping it.

Where should I keep my medicine?

Keep out of the reach of children.

Store between 20 and 25 degrees C (68 and 77 degrees F). Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

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