Tofacitinib - Medication Information

What is tofacitinib?
Tofacitinib (brand name: Xeljanz®) is a medication used to treat ulcerative colitis. It is in a class of medications called Janus kinase (JAK) that slow down the immune system’s activity to heal inflammation.

How is tofacitinib given?
Tofacitinib comes as a tablet, or pill, taken by mouth. It is typically taken at a dose of 10 mg, 2 times a day. Once the medication starts working, the dose can be lowered to 5 mg, 2 times a day.

When can I expect tofacitinib to work?
Tofacitinib works for most patients, usually soon after starting the medication. Some patients may feel an improvement in symptoms within the first week of starting tofacitinib. Some patients may need to give it some time for the medication to start working. Typically, up to 2 months is required to see a benefit. If a patient does not see any improvement after taking the medication for 2 months, the likelihood of it working for them at all is low.

What tests are needed while I am on tofacitinib?
Before beginning tofacitinib treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood counts and liver tests are done every 4 months while on tofacitinib.

Tofacitinib can increase cholesterol levels. Therefore, cholesterol (lipid) panel checks are recommended before and periodically while on tofacitinib.

What are the potential side effects of tofacitinib?
Side effects of tofacitinib may include:

- **Allergic reaction:** Patients may develop allergic reactions to tofacitinib as with any other medication. Reactions may include rash, hives, swelling of the lips or throat. This is uncommon and can be treated with steroid and anti-histamine medications.

- **Infection:** As with other medications that act on the immune system, tofacitinib can increase your risk of infections. Upper respiratory tract infections (cough, runny nose, sneezing, etc.) were the most common side effect, but only occurred in a few patients. Serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.

- **Shingles:** Tofacitinib may also increase the risk of a shingles infection (Herpes zoster). The shingles vaccine 2-dose series (brand name: Shingrix®) is recommended.

- **High cholesterol:** Tofacitinib can increase both good and bad cholesterol levels. While it has not shown to increase heart disease risk, some patients need to start a cholesterol lowering medication.

- **Blood clot:** In a research study, older patients with heart disease risk factors on tofacitinib for rheumatoid arthritis had a slightly increased risk of blood clots in the vein (venous thromboembolism). However, this increased risk of blood clots was not seen in patients with inflammatory bowel disease. It is still a warning on the medication regardless of the medication’s indication, so we like to inform patients about this listed side effect.
Lymphoma: Tofacitinib can also increase the risk of lymphoma, a form of cancer of the lymph node. The risk is low, but patients who are current or past smokers may have a higher risk.

Please see the medication package insert for the full list of potential side effects.

Is tofacitinib safe during pregnancy and breastfeeding?
There is very limited information on the use of tofacitinib during pregnancy or breastfeeding. The safety of the medication is unknown at this time. Women and men on tofacitinib have not been associated with fertility problems, miscarriages, birth defects, preterm birth, stillbirths, or other pregnancy-related problems. Out of precaution, do not breastfeed while on tofacitinib and for at least 1 day after stopping it.

If you are on tofacitinib and plan to become pregnant, please discuss with your provider.

How can I take care of my health while on tofacitinib?
It is important to be up to date with your health maintenance while on tofacitinib. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should only get the recombinant shingles vaccine (brand name: Shingrix®). Do not get the older shingles vaccines that contain the live but weakened virus. You should not get any live virus vaccines while on tofacitinib or for 3 months after stopping it.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up to date on all your vaccines and cancer screening.

What if my out-of-pocket costs are high with this treatment?
Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturer of tofacitinib has a patient assistance program called Xelsource for patients on the medication. Please go to https://xelsource.cp360.cardinalhealth.com/enrollment/registration for more information on this program.

What if I have questions about tofacitinib?
Talk with your provider about any questions or concerns you may have about tofacitinib.

This document has been reviewed for plain language by Blum Center staff.