

TOFACITINIB

What is Tofacitinib?

Tofacitinib (Xeljanz®) is an antibody against a group of enzymes (Janus kinases, JAK) that trigger inflammation. It is approved for the treatment of ulcerative colitis.

How is it administered?

Tofacitinib is an oral medication that is taken twice daily. It is typically given at a dosage of 10mg twice daily. Once a person has responded to it, the dose can be reduced to 5mg twice daily.

When can I expect to respond to Tofacitinib?

Some patients may feel a benefit within the first week of initiating therapy. Typically, up to 8 weeks is required to see a benefit.

Approximately 6 out of 10 patients will respond to Tofacitinib, usually soon after starting therapy. If a person has not responded by 2 months, likelihood of future response is low but some patients may have delayed response.

What testing is needed on Tofacitinib therapy?

You will need blood testing to check for exposure to hepatitis B and tuberculosis infection prior to beginning treatment with Tofacitinib. You may also need testing for tuberculosis exposure annually. Blood counts and liver tests are routinely drawn every 4 months while on Tofacitinib.

Tofacitinib has been associated with an increased levels of blood cholesterol. Therefore, cholesterol (lipid) panel checks are recommended prior to and periodically after starting treatment.

What are the potential side effects related to Tofacitinib?

Patients may develop allergic reactions to Tofacitinib as with any other medication.

As with other medications that act on the immune system, Tofacitinib can increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people. Significant medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Tofacitinib may also increase the risk of shingles infection (Herpes zoster). This risk is about 5% with the 10mg twice daily dose and 2-3% with the lower dose.

It can result in increase in cholesterol levels, though the increase is in both good and bad cholesterol components. There has been no reported increase in cardiovascular risk because of this but some patients need to start a cholesterol lowering medication.

In a clinical trial of older patients with rheumatoid arthritis with cardiac risk factors, there was a slight increase in risk of blood clots (venous thromboembolism) with tofacitinib.

Tofacitinib can also increase the risk of lymphoma, a form of cancer of the lymph node. The frequency of this in the general population is estimated to be around 2 out of 10,000 people. In those on Tofacitinib, this risk may increase to 3-4 in 10,000.

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

Is Tofacitinib safe during pregnancy and breast feeding?

Maternal and paternal use of Tofacitinib has not been associated with impairment of fertility, miscarriage, birth defects, preterm birth, still births, or other adverse pregnancy outcomes. However, there is very limited data on safety of tofacitinib during pregnancy or breastfeeding. If you are on tofacitinib and are contemplating pregnancy, please discuss with your provider.

Health maintenance on Tofacitinib therapy

It is important to be up to date with your health maintenance while on Tofacitinib therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines. Specifically, you should consider receiving the shingles vaccine. However, you should only receive the recombinant shingles vaccine (Shingrix®) and not the older shingles vaccines that contains the live but weakened virus. You should not receive live virus vaccines while on Tofacitinib therapy or within 3 months of stopping (or starting it).

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and dermatologic (skin check-ups) for both men and women. Make sure to speak to your primary care doctor about whether you are up-to-date on all your cancer screening and immunizations.

What if my out-of-pocket costs are high with this treatment?

There are a number of foundations that provide assistance to cover cost for patients on Tofacitinib therapy. The manufacturer of Tofacitinib has a patient assistance program for patients on Tofacitinib, called Xelsource. Please go to <https://uc.xeljanz.com/financial-support> for more information on this program.