

# Tofacitinib for IBD

## Points to remember

- Tofacitinib is a safe and effective medication to treat ulcerative colitis.
- Always attend your scheduled clinic appointments to ensure that you have access to an approved prescription in time for your next tofacitinib supply.

## What is tofacitinib and how does it work?

Tofacitinib is a drug known as a Janus Kinase (JAK) inhibitor. JAKs are enzymes that trigger the body's immune response which causes inflammation in ulcerative colitis. By blocking the action of JAK enzymes, tofacitinib reduces inflammation in the bowel and allows it to heal.

## Why have I been prescribed tofacitinib?

Tofacitinib is used to treat moderate to severe ulcerative colitis. It is prescribed if other medications have not worked or are not suitable for you.

## Important information about your access to tofacitinib

Tofacitinib is an expensive medication. Hence, it is subject to strict governmental restrictions and regulations to be subsidised on the PBS. To ensure ongoing supply of tofacitinib, you will be required to undergo assessment of your inflammatory bowel disease (IBD) every 6 months. This may include regular blood tests and an appointment with your IBD team.

## What checks do I need to have before starting tofacitinib?

Before you start tofacitinib, your IBD team may request blood tests including your full blood count, liver function tests, kidney function tests and cholesterol level. Your blood pressure may also be checked.

You will also be screened to check you are up to date with your vaccinations and for certain infections before starting treatment. The screening may include blood tests and a chest x-ray to assess infection risk. You may be advised to have one or more vaccines prior to commencing tofacitinib. Please refer to the [Vaccinations and IBD information sheet](#).

## What is the normal dose of tofacitinib?

Tofacitinib is usually commenced at a dose of 10mg twice a day for eight weeks and then reduced to 5mg twice a day (maintenance dose) depending on your response. In some cases, you may need to take the starting dose of 10mg twice a day for longer than eight weeks.

Your IBD team will monitor your response to this medication. You may need a higher dose depending on your disease and response to therapy.

Your IBD team will provide you with information on your dosage and when to have your blood tests taken.

## How do I take tofacitinib?

Tofacitinib tablets should be swallowed whole. They can be taken with or without food.

## How long will I be on tofacitinib?

If you respond to tofacitinib it may be used for the long term.

## What checks will I need while I am taking tofacitinib?

Regular blood tests are very important as tofacitinib can suppress normal bone marrow function and cause liver complications. Regular blood tests can pick up abnormalities in the blood that may not produce symptoms straight away. When you are on a stable dose of tofacitinib you may only require blood tests every 3-6 months.

Tofacitinib can increase cholesterol levels in some people. Your IBD doctor will check your cholesterol level before starting treatment and 4-8 weeks after. Some patients may need cholesterol lowering medication.

## Fertility, pregnancy and breastfeeding

There is limited information available on the use of tofacitinib in pregnancy and breastfeeding. Therefore, the use of tofacitinib in pregnancy is not recommended. Women of childbearing age on tofacitinib should take reliable contraception. Tofacitinib should be stopped at least 3 months before any planned pregnancy. Tell your doctor if you are thinking of becoming pregnant or find out you are pregnant.

It is not recommended to breastfeed whilst taking tofacitinib and for a period of time afterwards, while the medication is still in your body. Speak to your IBD team or lactation nurse before breastfeeding if you have recently stopped tofacitinib.

## What are the possible side effects of tofacitinib?

All medications can cause side effects, although not everyone experiences them. Report any side effects to the IBD team so they can be monitored.

### Common side effects:

- Some patients can experience headache, aches and pains, fever, flu-like symptoms, nausea (feeling sick) or diarrhoea. Often, these symptoms will resolve as the body becomes used to the new medication. Some patients may need to swap to an alternative medication.
- High blood pressure.
- High blood cholesterol.
- Tofacitinib may increase your risk of infections such as the common cold, and sometimes other more serious infections. Please contact your doctor or IBD team if you have any symptoms of infection, such as fever. This can sometimes be because your white blood (immune) cell count is too low, so this may need to be checked.
- Inflammation of the liver. If this occurs, stopping the medication or changing the dose can bring the liver tests back to normal. Monitor for signs including yellowing skin, dark urine and pale stools.

- Reduced kidney function. As tofacitinib is removed from your body through the kidneys, you may require a dose reduction if your kidney function is affected. You will have regular blood tests to monitor this.
- Shingles. This is a painful rash that can occur in patients who have had chickenpox previously. If you notice this, please see your GP, ideally within the first 3-5 days. You may need medication to treat this.

### Less common or rare side effects:

- Some patients may experience an allergic reaction to tofacitinib, such as a rash. Seek medical attention immediately if you develop swelling of your face, lips, tongue or throat or have difficulty breathing.
- Blood clots. Tofacitinib may increase your chance of developing a blood clot in the lungs or a blood vessel in the body. Seek medical attention immediately if you experience difficulty breathing or have swelling, pain or redness in your legs or arms.
- Tofacitinib can uncommonly increase the risk of other serious infections. This may include tuberculosis, pneumonia and chicken pox. You will be screened for this risk and vaccinated where possible.
- Taking tofacitinib may increase your risk of getting some types of cancer, including skin cancer and lymphoma (cancer of the lymph glands). These risks are very small and need to be balanced against the benefits of taking the drug. Please discuss any concerns with your IBD team.

## What can I do to keep myself healthy on tofacitinib?

- Avoid close contact with people with transmissible infections. Tell your doctor if you have come in contact with anyone who has an infectious condition such as chicken pox, shingles, whooping cough or measles.
- You should have the flu vaccine every year, and the COVID-19, pneumonia, and human papilloma virus (HPV) vaccines according to the recommended schedule. You should not have live vaccinations while taking tofacitinib, and for some time after stopping it. Please refer to the [Vaccinations and IBD information sheet](#) for further information.
- Women should have regular cervical screening tests as recommended by your GP.

- You should use a strong sunscreen and protect your skin when outside. Annual skin checks are recommended.
- Always check with your IBD team before starting new medications to avoid unwanted interactions.

*Contact the IBD team or your GP if you have an infection or persistent fever.*

This information leaflet has been designed to provide you with some important information about tofacitinib. This information is general and not intended to replace specific advice from your doctor or any other health professional. For further information please speak to your pharmacist, doctor or IBD nurse.

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