

# Tofacitinib for IBD

## Points to remember

- Tofacitinib is a safe and effective medicine to treat ulcerative colitis.
- Always attend your scheduled clinic appointments to ensure that you have an approved prescription available when you need to get your next supply of tofacitinib.

## What is tofacitinib and how does it work?

Tofacitinib is a medicine known as a 'Janus kinase (JAK) inhibitor'. JAKs are enzymes that trigger the body's immune response, which causes inflammation if you have a type of inflammatory bowel disease (IBD) known as 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 medicines have not worked or are not suitable for you.

## How do I get tofacitinib?

Tofacitinib is an expensive medicine, so there are strict government restrictions and regulations to make it available at a subsidised (lower) price on the PBS. To ensure you can keep taking tofacitinib, you will need to have your IBD assessed every 6 months. This may include regular blood tests and an appointment with your IBD team.

## What checks do I need to have before I start taking tofacitinib?

The Therapeutic Goods Administration says that tofacitinib should only be used if there are no other better treatments for people who:

- have or previously had heart disease or other cardiovascular risk factors (such as people who have smoked for a long time, or used to)
- have or previously had cancer
- are aged 65 years or older.

Before you start taking 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 for infections and to check you are up to date with your vaccinations before starting treatment. This screening may include blood tests and a chest x-ray to check your risk of infection. You may be advised to have one or more vaccinations before you start taking tofacitinib. Please see the [IBD – Vaccinations information sheet](#) for more information.

## What is the normal dose of tofacitinib?

You will usually start taking tofacitinib at a dose of 10 mg twice a day for 8 weeks. Then it will be reduced to 5 mg twice a day (known as a 'maintenance dose'), depending on how your body responds. In some cases, you may need to take the starting dose of 10 mg twice a day for longer than 8 weeks.

Your IBD team will monitor your body's response to this medicine. You may need a higher dose depending on your disease and response to the treatment.

Your IBD team will give you information about your dosage and when to have blood tests done.

## How do I take tofacitinib?

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

## How long will I need to take tofacitinib?

If your IBD gets better when you are taking tofacitinib, it may be used for the long term.

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

Regular blood tests are very important because tofacitinib can interfere with normal bone marrow function and can cause liver complications. Regular blood tests can pick up abnormalities in the blood that may not produce symptoms straight away. When you are taking a stable dose of tofacitinib, you may only need blood tests every 3–6 months.

Tofacitinib can increase cholesterol levels in some people. Your IBD doctor will check your cholesterol level before you start treatment and 8–12 weeks after starting treatment. Some people may need cholesterol-lowering medicine.

## Fertility, pregnancy and breastfeeding

There is limited information about whether tofacitinib is safe for pregnant and breastfeeding women to use, so it is not recommended to use it during pregnancy or while breastfeeding.

Women of childbearing age who are taking tofacitinib should use reliable contraception. You should stop taking tofacitinib at least 3 months before any planned pregnancy. Tell your doctor if you are thinking of becoming pregnant or find out that you are pregnant.

It is not recommended to breastfeed while taking tofacitinib and for some time afterwards, while the medicine is still in your body. Talk to your IBD team or lactation nurse before breastfeeding if you have recently stopped taking tofacitinib.

## What are the possible side effects of tofacitinib?

All medicines can cause side effects, although not everyone experiences them. Report any side effects to your IBD team so they can monitor them.

### Common side effects:

- **Headaches, aches and pains, fever, flu-like symptoms, nausea (feeling sick) or diarrhoea:** these symptoms will often go away as your body becomes used to the new medicine, but some people may need to swap to a different medicine

- **High blood cholesterol**
- **An increased risk of infections like 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 a 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 happens, stopping the medicine or changing the dose can bring the results of your liver tests back to normal; monitor for signs including yellowing skin, dark urine (wee) and pale stools (poo)
- **Reduced kidney function:** as tofacitinib is removed from your body through the kidneys, you may need a lower dose 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 people who have previously had chickenpox; if you notice a rash, please see your GP, ideally within the first 3–5 days, as you may need medicine to treat this
- **High blood pressure.**

### Less common or rare side effects:

- **An allergic reaction to tofacitinib, such as a rash:** seek medical attention immediately if you have any swelling of your face, lips, tongue or throat or have difficulty breathing
- **Blood clots in the veins of the legs (deep vein thrombosis) and lungs (pulmonary emboli):** seek medical attention immediately if you have chest pain, difficulty breathing, or swelling, pain or redness in your legs or arms
- **Heart-related problems and clots in arteries:** seek medical attention immediately if you have chest pain, difficulty breathing, or numbness or weakness in your face, arms or legs
- **An increased risk of other serious infections, such as tuberculosis, pneumonia and chicken pox:** you will be screened for this risk and vaccinated if possible
- **An increased risk of some types of cancer, including skin cancer and lymphoma (cancer of the lymph glands):** this risk is very small and needs to be balanced against the benefits of taking the medicine; please discuss any concerns you have with your IBD team.

## What can I do to keep myself healthy while taking tofacitinib?

- Avoid close contact with people who have transmissible infections. Tell your doctor if you have come into 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 papillomavirus (HPV) vaccines according to the recommended schedule. Your IBD team may recommend you have the recombinant ('non-live') shingles vaccine. You should not have any 'live' vaccines while taking tofacitinib and for some time after stopping it. Please see the [IBD – Vaccinations information sheet](#) for more 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 to take any new medicines, to avoid unwanted interactions with tofacitinib.

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

This information leaflet has been designed to give you 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 more information, please talk to your pharmacist, doctor or IBD nurse.

## Acknowledgements:

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