



TOFACITINIB

INTRODUCTION

This information is for you if you're considering or have been prescribed treatment with tofacitinib (Xeljanz) for Ulcerative Colitis.

It looks at:

- what you can expect from treatment
- how the medicine works
- possible side effects
- stopping or changing treatment.

Our information can support you to make an informed decision about treatment that's right for you.



I had multiple failed attempts at other medications and was beginning to lose hope. Then I was on tofacitinib successfully for two and a half years. My energy came back and I was able to do so much more with my life.



Lottie, age 31
Living with Ulcerative Colitis

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TOFACITINIB

OTHER NAMES FOR THIS MEDICINE

Tofacitinib is also known by the brand name Xeljanz.

WHY AM I BEING OFFERED TREATMENT WITH TOFACITINIB?

Tofacitinib is available to treat moderately to severely active Ulcerative Colitis in adults. It can be an option when other treatments including steroids, immunosuppressants (such as azathioprine, mercaptopurine, methotrexate) or biological drugs (infliximab, adalimumab, golimumab, vedolizumab) haven't been effective. Or if other treatments have stopped working or given you side effects that are difficult to manage.

Choosing between tofacitinib, biologic medicines and surgery can be a big decision. Talk to your doctor about the possible advantages and disadvantages of all the options.

HOW EFFECTIVE IS TOFACITINIB?

The aim of treatment with tofacitinib is to:

- reduce inflammation in the gut (bring about remission)
- prevent flares (maintain remission)
- improve your well-being by reducing or stopping symptoms including diarrhoea, bleeding and pain.

Although tofacitinib doesn't work for everyone, several large studies have shown that it can be effective in bringing about and maintaining remission in people with Ulcerative Colitis when other drugs haven't been helpful.

Two large studies found that eight weeks after starting treatment with tofacitinib, around 3 out of 10 people noticed a positive difference and over half of those people were in remission.



3 out of 10 people found a positive difference after eight weeks of taking tofacitinib.

The people who found tofacitinib was effective continued to be monitored for a further year, and at the end of that time 4 out of 10 people were still in remission.

Although this is a new treatment for people with Ulcerative Colitis, tofacitinib has been used as a treatment for people with some types of arthritis for a few years.

HOW DOES TOFACITINIB WORK?

Tofacitinib is a type of drug called a Janus kinase (JAK) inhibitor. JAKs are enzymes that are involved in activating the body's immune response, which causes the gut inflammation in Ulcerative Colitis. Tofacitinib blocks this process, and so reduces inflammation.

Tofacitinib is a small molecule drug, which means that it's less likely to stop working over time than biologic medicines such as infliximab, adalimumab, golimumab or vedolizumab. Biologics are larger molecules that the immune system sometimes recognises as a foreign substance and thinks is harmful. It then produces proteins called antibodies to the biologic medicine and these prevent it from working as well.

HOW LONG DOES IT TAKE TO WORK?

If tofacitinib works for you, you'll usually see an improvement within eight weeks. But some people may find that they begin to feel better as soon as three days after starting treatment.

If your condition hasn't changed after the first eight weeks, your IBD team may decide to continue with the medication for a further eight weeks. But if treatment hasn't worked for you after this time (16 weeks in total), it should be stopped as it's not the right treatment for you. Your IBD team will talk to you about the other options available.

HOW DO I TAKE TOFACITINIB?

Tofacitinib is a tablet that is usually taken by mouth twice a day.

- one tablet in the morning
- one tablet in the evening

Try to take your tablets at a similar time every day. You can take it with or without food, and if you have difficulty swallowing the tablet, it can be crushed and taken with water.

HOW LONG WILL I BE TAKING TOFACITINIB?

Your treatment with tofacitinib will be reviewed after one year. If tofacitinib works for you this can be continued.

WHAT'S THE NORMAL DOSE?

Treatment begins with a dose of 10mg twice a day for eight weeks, known as the induction dose. If the treatment works for you this will be followed by 5mg twice a day going forward, known as the maintenance dose. Your treatment will be reviewed after one year.

If your Ulcerative Colitis flares whilst on 5 mg twice a day, your dose can be increased back to 10mg twice a day to try to reduce the inflammation and symptoms. However there is a higher risk of side effects on the 10mg dose.

CAN TOFACITINIB BE USED IN COMBINATION WITH OTHER DRUGS TO TREAT ULCERATIVE COLITIS?

Tofacitinib is sometimes given with steroids (corticosteroids) to help bring about remission when you start treatment. The aim is to stop or reduce steroids when the tofacitinib starts working, as serious infections happen more often in people who also take steroids.

If you're taking mesalazine you can stay on this whilst taking tofacitinib.

But you shouldn't be prescribed tofacitinib with a biologic medicine such as infliximab, adalimumab, golimumab, vedolizumab or immunosuppressants such as azathioprine, methotrexate or mercaptopurine. If you are taking any of these medications, it is important that you stop them before starting tofacitinib.

IS IT SAFE TO TAKE OTHER MEDICINES WITH TOFACITINIB?

Always tell your doctor if you are taking any other medicines, because they may interact with tofacitinib and cause unexpected side effects. This includes medicines that you buy yourself, often known as over-the-counter medicines. Or any herbal, complementary or alternative medicines such as St John's Wort, sometimes used for low mood, which may reduce tofacitinib effectiveness.

Medicines that contain any of the following may also affect how the tofacitinib works:

- antibiotics used to treat bacterial infections such as clarithromycin and rifampicin.
- antifungals used to treat fungal infections such as fluconazole, ketoconazole, clotrimazole, itraconazole, and voriconazole.

This isn't a full list so talk to your IBD team or pharmacist before you take any other medicines.

“
Tofacitinib is great as it is just a pill and can be taken in the comfort of your own home. Other drugs I tried meant going into hospital to have infusions. I've been in remission on tofacitinib for three years now
”

Shirley, age 47
Living with Ulcerative Colitis

DO I NEED ANY CHECKS BEFORE I START TREATMENT?

Before you start treatment your IBD team will check that this treatment is right for you.

Blood tests

You'll have blood tests to check your full blood count, kidney function and lipids. Your IBD team may want to check if you've been exposed to a variety of viral infections including HIV, Hepatitis B and C, EBV (Epstein-Barr virus) and varicella to ensure that it is a safe and appropriate. They will also screen for tuberculosis.

Vaccinations

Tofacitinib acts on the immune system and can make you more susceptible to infections. To reduce this risk, you should have all the vaccinations you need before you start treatment.

If these are "live" vaccines such as the varicella zoster vaccination for shingles, you'll need to have this at least two weeks and ideally four weeks before you start the tofacitinib. See the section **Can I have immunisations while on tofacitinib?**

Make sure your IBD team know if you have a history of:

- **Tuberculosis.** If you have any history of tuberculosis (TB) or any recent exposure to people with TB. You should not be given tofacitinib if you have active TB, and if you have underlying, inactive TB, this will need to be treated before you start therapy. Most doctors now use a blood test to check for underlying or inactive TB, but you may be given a chest x-ray as well.
- **Infections.** If you have a history of infections or currently have an infection, such as tonsillitis or a urinary tract infection, or have symptoms such as feeling feverish or generally unwell. Your tofacitinib treatment may need to be postponed until the any infection has cleared. This is because taking tofacitinib could make the infection worse.
- **Heart problems.** If you have heart problems such as congestive heart failure, ischemic heart disease or a history of fainting, tofacitinib may make your symptoms worse.
- **Blood clots.** Tofacitinib may increase the risk of blood clots in the legs (deep vein thrombosis) or lungs (pulmonary embolism). If you have a history of previous blood clots this medication is not right for you and you will not be offered this.
- **Cancer.** If you have already had cancer you may have a slightly increased risk of developing some types of cancer including lymphoma and some types of skin cancer. This is because tofacitinib affects the way your immune system works.
- **Liver problems.** If you've previously had hepatitis you may need regular checks for this as tofacitinib may increase the risk of you having hepatitis again.

DO I NEED ONGOING CHECKS?

You should be offered blood tests after eight weeks of treatment and then every three months during treatment to monitor your white blood cells (lymphocytes, neutrophils) and red blood cells (haemoglobin), as the medication can cause a reduction in these. Your liver function and cholesterol will be routinely monitored too as tofacitinib can increase cholesterol levels for some people.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS

Because tofacitinib affects the way your immune system works, you may be more likely to get infections. Even a mild infection such as a cold or sore throat could develop into a more serious illness. Tell your IBD team if you begin to feel unwell and think you might have an infection.

Your doctor will give you a **Patient Alert Card** which contains important information about what to look out for.

To reduce risks:

- **Have the annual flu vaccination.** You may also be advised to have a pneumonia vaccination. If left untreated pneumococcal infections can lead to pneumonia (inflammation of tissue in the lungs) septicaemia (a kind of blood poisoning) and meningitis (an infection of the protective membranes that surround the brain and spinal cord).
- **Try to avoid close contact with people who have infections.** This includes viruses and bacteria that cause chickenpox and shingles, measles, and pneumococcal disease. Contact your IBD team or doctor if you begin to feel unwell and think you may have caught an infection.
- **Take care in the sun.** There is a small increased risk of skin cancers for people who take tofacitinib. Take precautions in the sun including using sunblock, wearing a hat, covering your skin when you are out in strong sunshine and don't use sun beds.

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF TAKING TOFACITINIB?

Like all drugs, tofacitinib can have unwanted side effects, although not everybody will get them. Some side effects may be quite mild and go away on their own. Others can be more serious and need treatment or may mean that tofacitinib isn't right for you.

Some of the most common side effects are mentioned below. You can find a full list in the Patient Information Leaflet (PIL) that comes with your medicine or at www.medicines.org.uk.

IMMEDIATE REACTIONS

Any medication can cause an allergic reaction. **Tell your doctor immediately if you develop any of the following symptoms:**

- difficulty breathing or swallowing
- rash, hives (swollen red patches of skin) or other signs of allergic reaction
- swollen face including lips and mouth or hands and feet

COMMON SIDE EFFECTS

The most common side effects that people experience when are taking tofacitinib are headache, runny or stuffy nose and slight swelling at the back of the throat (nasopharyngitis), feeling sick (nausea) and joint pain (arthralgia).

OTHER SIDE EFFECTS

Because tofacitinib acts on the immune system it can have some serious side effects. Your IBD team will continue to monitor you to minimise risks but let them know if you:

- think you have an infection including having a fever, sore throat and achiness
- have a bump or open sore which is not healing.
- have gut symptoms that are not improving or are getting worse, especially if you also have a fever. There may also be a risk of gut perforation.

There is an increased **risk of shingles** (herpes zoster reactivation). If you develop blister like skin eruptions, you should stop the medication immediately and contact your IBD team. You can normally restart the drug once the rash has healed.

Tofacitinib may increase the **risk of blood clots** in your legs (deep vein thrombosis) or lungs (pulmonary embolism). Seek urgent medical care if you develop swelling of your legs or arms with reddened and swollen skin. Or breathlessness, chest or back pain whilst you're on this medication.

Tofacitinib may **raise levels of blood cholesterol** in some people. Your IBD team will monitor this with regular blood tests.

If you are worried about any new or ongoing symptoms talk to your IBD team. The Patient Information Leaflet (PIL) that comes with your medicine has a full list of side effects or at www.medicines.org.uk.

CAN I HAVE IMMUNISATIONS WHILE ON TOFACITINIB?

It is not safe to have "live" vaccines when you're taking this medicine. Live vaccines contain viruses that have been weakened, but not destroyed. People who are taking medicines which affect the immune system such as tofacitinib may not be able to produce antibodies quickly enough and risk becoming infected by the disease.

Live vaccines include polio, yellow fever, rubella (German measles), BCG (tuberculosis), MMR (measles, mumps and rubella) and Zostavax (shingles). However, you may be able to have the inactivated polio vaccine. If anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions.

DOES TOFACITINIB AFFECT FERTILITY OR PREGNANCY?

You should not take tofacitinib if you are pregnant or planning to become pregnant. Tofacitinib can't be taken in pregnancy because of the risk of damage to the developing baby. Use effective contraception whilst you are taking this medicine and for four weeks after you stop taking this if you could get pregnant.

You can use oral contraception when you're taking tofacitinib. Our information sheet on **Reproductive Health** can help you decide on the right contraceptive for you based on your Colitis symptoms.

If you do become pregnant whilst you're taking tofacitinib

Tell your IBD team immediately. There are reports of some women who have become pregnant while taking tofacitinib, mostly in early pregnancy. In these women there wasn't any increase in miscarriage or birth defects in the baby.

If you are planning to become pregnant

We don't know yet if tofacitinib affects fertility in men or women. If you're planning to get pregnant tell your IBD team as you will need to stop taking tofacitinib.

What about breastfeeding?

It's not yet known whether tofacitinib is present in breast milk so as a precaution you should avoid breastfeeding.



CAN I DRINK ALCOHOL?

Alcohol isn't known to have any interaction with tofacitinib.



STOPPING OR CHANGING TREATMENT

There are a few reasons why you and your IBD team might think the time is right for you to stop or change treatment.

Tofacitinib stops working - because tofacitinib is a small molecule, antibodies to the drug are not likely to form. This means that tofacitinib is less likely than biologics to stop working over time. But if it does stop working you can increase the dose back to 10mg twice daily to recapture the previous benefit, although this does increase the risk of side effects. If you stop the drug for a period of time it can be re-started later without an increased risk of side effects or lack of response.

Side effects - if side effects are serious or difficult to manage, your IBD team will talk to you about your options.



WHO SHOULD I TALK TO IF I'M WORRIED?

If you're worried about your tofacitinib treatment or have any questions, talk to your IBD team. They should be able to help you with any queries such as why it's been prescribed, what the correct dose and frequency are, what monitoring is in place, and what alternatives may be available for you.

Your IBD team should give you clear information, talk with you about your options and listen carefully to your views and any worries or concerns you may have. The choice of treatment between tofacitinib, biological drugs and surgery should be made after talking with your IBD team about the possible advantages and disadvantages of all the options. You can also talk to the Crohn's & Colitis UK **Helpline**.

HELP AND SUPPORT FROM CROHN'S & COLITIS UK

We're here for you whenever you need us. Our award-winning publications on Crohn's and Colitis have the information you need to help you manage your condition.

We have information on a wide range of topics, from individual medicines to coping with symptoms and concerns about relationships, school and employment. We'll help you find answers, access support and take control.

All publications are available to download from our website:
crohnsandcolitis.org.uk/publications

Health professionals can order some publications in bulk by using our online ordering system, available from the webpage above. If you would like a printed copy of a booklet or information sheet, please contact our helpline.

Our helpline is a confidential service providing information and support to anyone affected by Crohn's or Colitis.

Our team can:

- help you understand more about Crohn's and Colitis, diagnosis and treatment options
- provide information to help you live well with your condition
- be there to listen if you need someone to talk to.
- help you understand and access disability benefits.
- put you in touch with a trained support volunteer who has personal experience of Crohn's or Colitis.

Call us on **0300 222 5700** or email **helpline@crohnsandcolitis.org.uk**. See our website for LiveChat: **crohnsandcolitis.org.uk/livechat**

Crohn's & Colitis UK Forum

This closed-group community on Facebook is for everyone affected by Crohn's or Colitis. You can share your experiences and receive support from others at: **facebook.com/groups/CCUKforum**

Help with toilet access when out and about

If you become a member of Crohn's & Colitis UK, you will get benefits including a **Can't Wait Card** and a **Radar key** to unlock disabled toilets. This card shows that you have a medical condition and combined with the Radar key will help when you need urgent access to the toilet when you are out and about. See our website for further information: **crohnsandcolitis.org.uk/membership** or call the membership team on **01727 734465**.



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We hope that you have found this leaflet helpful and relevant. If you would like more information about the sources of evidence on which it is based, or details of any conflicts of interest, or if you have any comments or suggestions for improvements, please email the Publications Team at publications@crohnsandcolitis.org.uk. You can also write to us at Crohn's & Colitis UK, 1 Bishops Square, Hatfield, Herts, AL10 9NE or contact us through the **Helpline: 0300 222 5700**.

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ABOUT CROHN'S & COLITIS UK

We are Crohn's & Colitis UK, a national charity fighting for improved lives today – and a world free from Crohn's and Colitis tomorrow. To improve diagnosis and treatment, and to fund research into a cure; to raise awareness and to give people hope, comfort and confidence to live freer, fuller lives. We're here for everyone affected by Crohn's and Colitis.

This publication is available for free thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis: call **01727 734465** or visit crohnsandcolitis.org.uk.