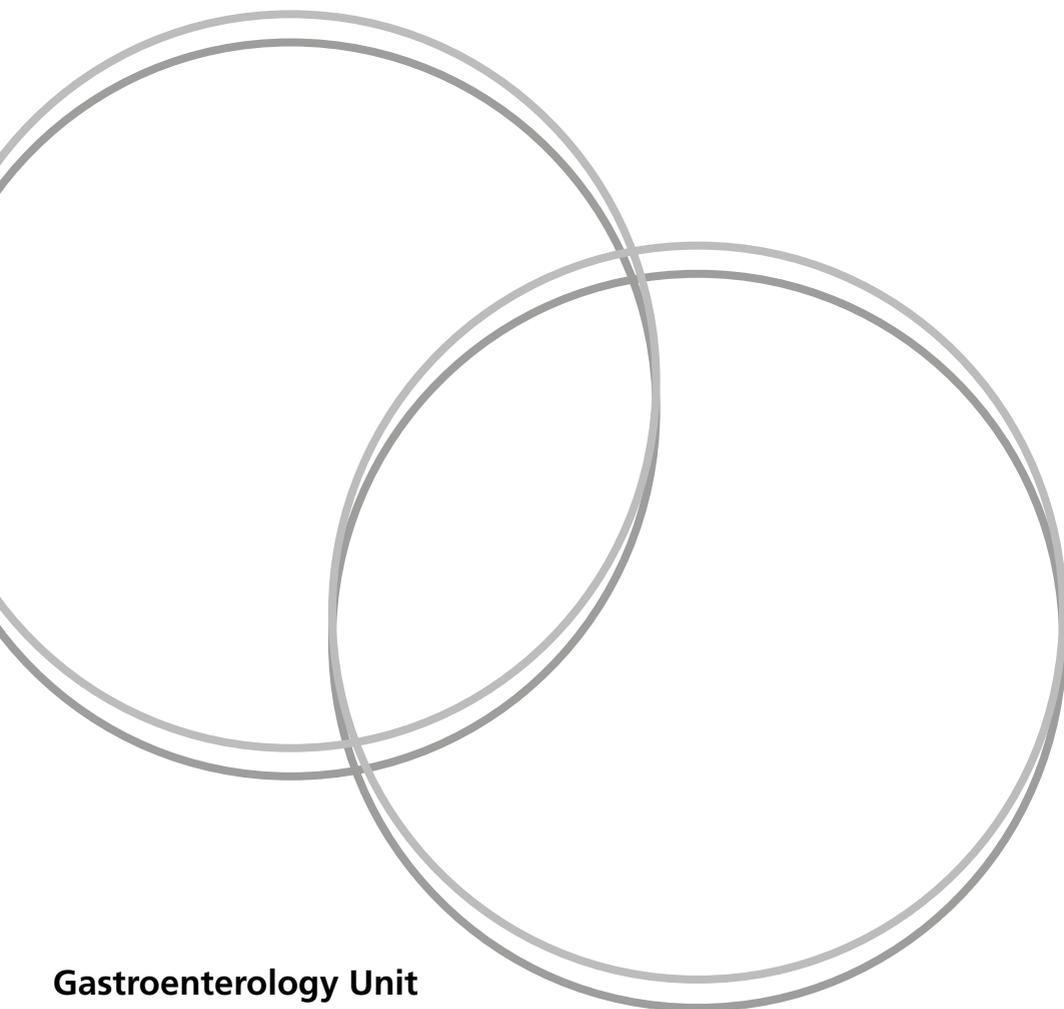


# Tofacitinib citrate (Xeljanz<sup>®</sup>)

**Medicines information for patients**



## **Tofacitinib citrate (Xeljanz®)**

This leaflet answers some of the common questions asked about tofacitinib citrate.

Further information can be found in the information leaflet supplied by the manufacturer (inside the box) or from your pharmacist, IBD nurse specialist or gastroenterologist.

## **Why am I having tofacitinib citrate?**

Tofacitinib citrate (usually just known as tofacitinib) is used in the treatment of moderately or severely active ulcerative colitis. It is usually recommended if your condition has not responded well or has stopped responding to corticosteroids (such as prednisolone), and/or an immunomodulator (such as azathioprine, mercaptopurine or methotrexate), or a biologic (such as infliximab, adalimumab or vedolizumab). In addition, it can be used if you are unable to take these treatments or have become intolerant to them.

Tofacitinib is also used in the treatment of rheumatoid arthritis and psoriatic arthritis.

## **How does tofacitinib work?**

Tofacitinib belongs to a class of medicines called Janus kinase (JAK) inhibitors. JAKs are enzymes that play a role in activating the body's immune response. Tofacitinib inhibits (blocks) this process, which reduces the inflammatory process in ulcerative colitis.

## **Before starting treatment**

**You should tell your specialist doctor or nurse if you have had or currently have any of the following:**

- previous blood clots (pulmonary embolus or deep vein thrombosis 'DVT')
- family history of thrombosis (such as pulmonary embolus)
- heart failure or heart disease
- shingles
- any type of cancer (current or in the past) or are at high risk of developing skin cancer
- hormone replacement therapy or taking the oral contraceptive pill
- diverticulitis or stomach ulcers
- kidney problems
- high blood pressure
- high cholesterol
- tuberculosis
- hepatitis B or hepatitis C or any other liver disease.

## **What dose should I be taking?**

Tofacitinib is taken by mouth and is available as 5mg and 10mg film-coated tablets, which can be taken with or without food. The usual dose prescribed is 10mg twice a day for 8-16 weeks, followed by 5mg twice a day depending on your response, which will be monitored regularly. You must not adjust the dose prescribed unless told to do so by your doctor.

## **How long will it take to work?**

You will hopefully see an improvement in your symptoms within the first 8 weeks (sometimes much sooner than this). If there is no response within 16 weeks, we will stop the tofacitinib and offer an alternative treatment.

## **How long will I take it for?**

Your treatment will be reviewed regularly. If the tofacitinib is causing no problems, and your symptoms are well controlled, then you will continue taking it.

In clinical studies, more than half the people taking this medication responded to treatment and one third of people taking it had control of their symptoms without bleeding after one year.

## **Where do I get further supplies from?**

Tofacitinib is a specialist medicine, which can only be prescribed by the hospital IBD team and supplied by the hospital pharmacy. It cannot be prescribed by your GP.

Once treatment is started, it is important to make sure you always have an adequate supply of tablets. A gastroenterology pharmacist will discuss the supply process with you.

## **What happens if I forget to take a dose?**

You should not take a double dose to make up for a forgotten tablet. Take your next tablet at the usual time and continue as before. It is also important to contact the IBD team if you accidentally take too much tofacitinib.

Taking the doses at the same time each day will help you to remember to take it, or you could set yourself a timer or reminder.

## **Do I need any special checks whilst taking this medicine?**

You will have regular tests to check the medicine is working properly and to monitor for potential side effects. These will include blood tests, which check for infection, anaemia, cholesterol levels and liver function, which can be affected by the treatment. You may also have a sigmoidoscopy or colonoscopy, to assess your response to the treatment.

You will have an appointment every 3-6 months. If you repeatedly miss your appointments we will need to review whether you should continue this treatment. You should let us know if you are not able to attend, so we can offer you an alternative appointment.

## **Does tofacitinib interfere with other medicines?**

You should tell your specialist doctor or nurse or pharmacist about all medicines you are currently taking, even those not prescribed.

Tofacitinib should not be taken with any other immunosuppressant (such as azathioprine) or biological medication (such as infliximab), as this can increase the risk of side effects, including infection.

If you are prescribed antibiotics, including clarithromycin or rifampicin, or oral medication for a fungal infection (such as fluconazole, clotrimazole or ketoconazole), then you must let the IBD team know before you take it.

You should avoid having 'live' vaccines whilst taking tofacitinib. This includes:

- mumps, measles and rubella (MMR)
- yellow fever
- BCG
- some typhoid vaccines
- varicella vaccines.

If you need travel vaccines, or your doctor, nurse or pharmacist advise that you need a vaccine, always tell the healthcare professional that you are taking tofacitinib.

It is recommended that you have the seasonal vaccination against influenza, and pneumococcal polysaccharide vaccine (to protect against certain types of pneumonia), unless you have been told not to.

You should inform your nurse, doctor or pharmacist if you are going to receive any vaccination or have recently had a vaccination.

## **Is tofacitinib safe during pregnancy and breastfeeding?**

We cannot recommend taking tofacitinib during pregnancy or breastfeeding, as there is not enough evidence about how safe this would be for mother and baby.

If you are a woman of childbearing age (12-55 years), you should make sure that you are not pregnant before beginning treatment. We advise using birth control before starting treatment, as pregnancy tests may not reliably detect a pregnancy during the first month. You should also avoid becoming pregnant during treatment. You must use effective and reliable birth control during treatment with tofacitinib, and for at least 4 weeks after your last dose.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, you must discuss this with the IBD team before taking tofacitinib.

There is a detailed booklet on pregnancy and IBD available on the OUH website (see link on the back page of this leaflet) or from the Gastroenterology Outpatients Department at the John Radcliffe and Horton General Hospitals.

## What are the most common side effects?

Some of the most common side effects (affecting up to 1 in 10 people) include:

- infections
- herpes zoster (shingles)
- influenza
- sinusitis
- cough
- rash
- feeling tired
- nose/throat infections
- diarrhoea
- nausea and vomiting
- headache
- stomach ache
- joint pain (arthralgia).

**You should also refer to the patient information leaflet supplied by the manufacturer for other possible side effects.**

If you develop a serious infection we may stop the medication and restart it once the infection is treated.

You may be offered a herpes zoster (shingles) vaccination before starting treatment. Your specialist will discuss this with you.

**If you think you are experiencing any side effects that may be associated with the medicine, please talk to a member of the IBD team.**

**You should not stop taking the medicine unless advised to do so.**

## **Useful contacts**

### **Gastroenterology Pharmacist**

Tel: **01865 221 523**

Email: **ibd.homecare@nhs.net**

### **IBD advice line**

Tel: **01865 228 772**

Email: **ibd.advice@nhs.net**

**Keep all medicines out of the reach of children.**

**Never give any medication prescribed for you to anyone else.**

**It may harm them, even if their symptoms are the same as yours.**



## Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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[www.ouh.nhs.uk/information](http://www.ouh.nhs.uk/information)



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