

Filgotinib

This information is for people with [Ulcerative Colitis](#) who are taking filgotinib (Jyseleca). It is also for anyone who is thinking about starting treatment with filgotinib. This information can help you decide if filgotinib is right for you. It looks at:

- How filgotinib works.
- What you can expect from filgotinib treatment.
- Possible side effects.
- Stopping or changing treatment.

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Key facts about filgotinib

- Filgotinib is used to treat Ulcerative Colitis. It can help get your Colitis under control and keep it under control.
- Filgotinib is a tablet, taken by mouth once a day.
- Filgotinib affects the way your immune system works. This means your body may not be able to fight off infections as well. Contact your IBD team straight away if you think you have an infection.
- You should not have live vaccines while you are taking filgotinib. You can have non-live vaccines, like the annual flu jab and COVID-19 vaccines.

Other names for filgotinib

Filgotinib is also known by the brand name Jyseleca.

How filgotinib works

Filgotinib is a type of medicine called a Janus kinase (JAK) inhibitor. JAKs are proteins that play a part in activating the body's immune response. This can cause gut inflammation in [Ulcerative Colitis](#). Filgotinib blocks the effects of JAKs, reducing inflammation in the gut.

[Tofacitinib](#) is another JAK inhibitor that is used to treat Colitis. You may also hear JAK inhibitors called small molecule drugs.

Why you might be offered filgotinib

Filgotinib is used to treat moderate to severely active Ulcerative Colitis in adults. The aim of treatment is to get your Colitis under control and keep it under control.

Your IBD team might suggest filgotinib if standard treatments, a biologic medicine or tofacitinib:

- Have not worked or have stopped working, or
- Have caused side effects that are severe or difficult to manage, or
- Are not suitable for you.

Standard treatments for Colitis include [5-ASAs](#), [steroids](#), or immunosuppressants such as [azathioprine](#), [mercaptopurine](#) or [methotrexate](#). [Biologic medicines](#) include adalimumab, golimumab, infliximab, ustekinumab and vedolizumab. You do not need to have tried all of these before considering filgotinib.

Filgotinib is not recommended for use in children. This is because there is not yet any research in people under 18 years.

Filgotinib is not currently recommended to treat adults aged 75 years and older. Older people often have other health conditions, including serious infections. This can make the side effects of filgotinib more serious. There is no research about filgotinib as a treatment for Colitis in this age group.

Deciding which medicine to take

There are lots of things to think about when you start a new treatment. Your IBD team will discuss your options with you. When thinking about a new treatment you might want to consider the potential benefits, possible risks and the goals of your treatment. Some things to think about include:

- How you will take it.
- How well it works.
- How quickly it is likely to work.
- Side effects you might experience.
- Whether you need ongoing tests or checks.

- Other medicines you are taking.

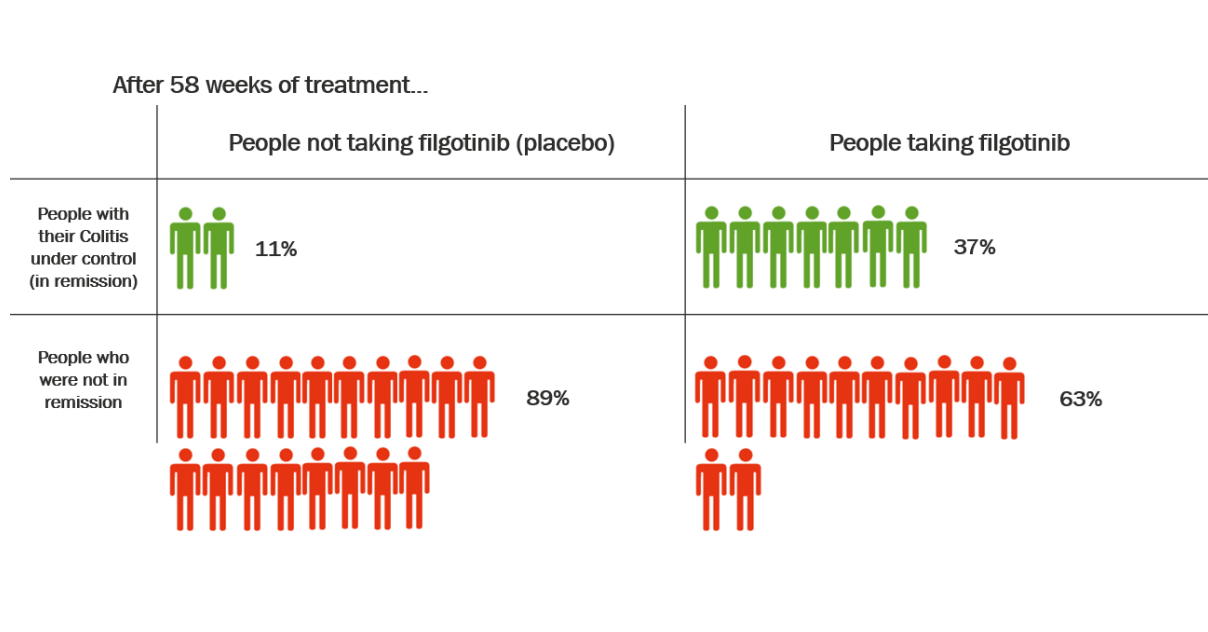
Our [Appointment guide](#) has a list of questions you might want to ask. It can help you focus on what matters most to you. You might find our information about other [medicines](#) and [surgery](#) for Colitis helpful.

How well does filgotinib work in Colitis?

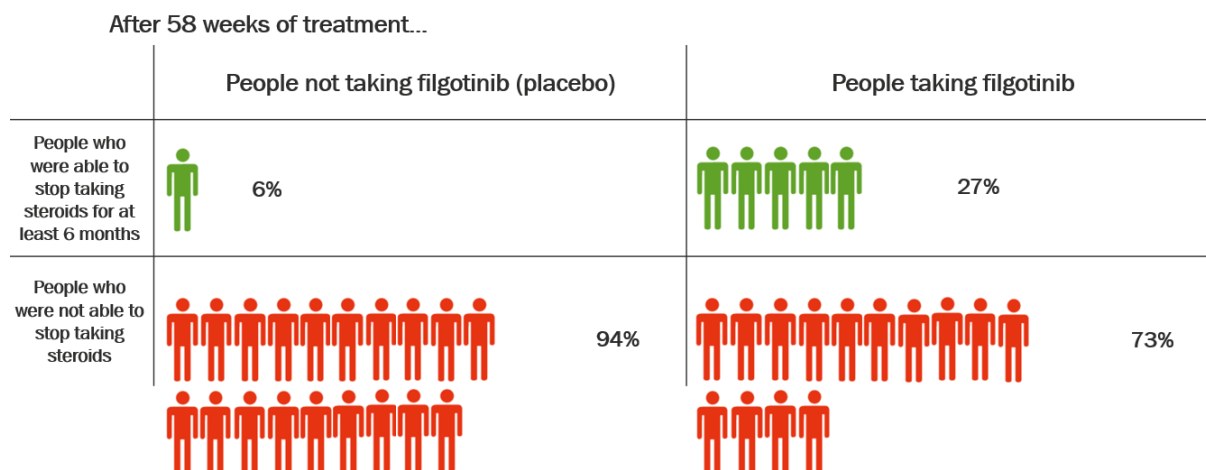
Find out more about how we [talk about the effectiveness of medicines](#).

Filgotinib can help to get Colitis under control and keep it under control (in remission). It can also reduce the need for long-term steroid treatment. But it does not work for everyone.

In one clinical trial, people took filgotinib or a placebo for about 1 year. A placebo is a dummy treatment that looks the same but does not have any medicine in it. At the end of the trial, more than three times as many people who took filgotinib were in remission compared with people who had taken a placebo.



Steroids are usually used to quickly reduce inflammation and control symptoms in people with Colitis. But they should not be taken in the long-term because of their side effects. One of the aims of treatment for Colitis is to keep people off steroids as much as possible. At the start of the trial between 2 and 4 in every 10 people in the study were taking steroids. The research looked at how many of these people were able to stop taking steroids during the trial. By the end of the trial, more people who took filgotinib were able to stop taking steroids for at least 6 months compared with people who took a placebo.



Longer trials are being done to see whether filgotinib continues to work after a year.

Filgotinib has not been compared directly with other treatments for Colitis.

How long does filgotinib take to work?

Everyone responds differently to a new medicine. If filgotinib is going to work for you, you will usually start to feel better within about 10 weeks. Some people may take a bit longer to start to feel better. In some people it can take up to 22 weeks (5 to 6 months) to get relief from symptoms. For some people, filgotinib does not relieve their symptoms at all.

Dose of filgotinib

Filgotinib can only be prescribed by a specialist IBD team and not your GP.

Filgotinib is taken as a tablet. Each tablet contains 100mg or 200mg filgotinib.

To get symptoms under control (induction treatment):

- The usual dose for induction treatment for Colitis is 200mg once a day.

To keep symptoms under control (maintenance treatment):

- The usual dose for maintenance treatment for Colitis is 200mg once a day.
- For those aged 65 years and above or who are at higher risk of blood clots, heart attack, stroke or cancer, the recommended dose for maintenance treatment is 100mg once a day. If you are in a flare-up, your IBD team may increase this to 200mg once a day.
- If you have kidney disease, you might also need to take a lower dose. The dose in moderate to severe kidney disease is 100mg once a day.

Try to take the tablet at a similar time each day. Swallow the tablet whole with a drink of water. Do not split, crush or chew the tablet before swallowing as it may change how much medicine gets into your body. You can take filgotinib with or without food.

Filgotinib tablets contain lactose. You should let your IBD team know if you have been told you have an intolerance to some sugars.

How long will you take filgotinib for?

Your IBD team will review your treatment every 6-12 months to check whether it is still the best option for you.

Stopping or changing treatment

There are a few reasons why you or your IBD team might think about stopping or changing your treatment:

- **Filgotinib hasn't worked**

If your Colitis has not improved within 5 to 6 months, your IBD team will probably suggest stopping filgotinib and trying another treatment. Your IBD team might suggest stopping filgotinib sooner if it is not working at all.

- **Filgotinib stops working**

It is possible that filgotinib will stop working for you over time. If this happens, your IBD team might suggest stopping filgotinib and trying another treatment.

- **You have side effects**

If you have side effects that are serious or difficult to manage, stopping filgotinib might be the best option for you.

Taking filgotinib with other medicines for Colitis

When you start taking filgotinib you might continue to take steroids, aminosaliclates (5-ASAs) and other immunosuppressant medicines such as [azathioprine](#), [mercaptopurine](#) or [methotrexate](#). If you are taking steroids when you start filgotinib, you may be able to reduce the dose of steroids if you respond well to filgotinib. Or you may be able to stop taking them altogether. Your IBD team will advise you about this.

It is important that you do not stop taking steroids without speaking to your IBD team.

You should not take biologic medicines or tofacitinib if you are taking filgotinib. If you are taking other immunosuppressant medicines as well as filgotinib, your immune system may be further suppressed.

Checks before starting treatment

Taking filgotinib can mean that your body is not able to fight off infections as well as it used to. It can also cause previous viral infections, such as shingles, to return. Before you start filgotinib, your IBD team will ask you some questions and do some tests. This is to make sure your risk from an infection is as low as possible. Tell your IBD team if:

- You have ever had tuberculosis (TB) or you have recently been in close contact with someone who has TB. If you have TB it will need to be treated before you start filgotinib. You will usually have a blood test or a chest X-ray to check for TB.
- You have ever travelled to or lived in a place where TB is very common or if you live with anybody who has had TB.
- You have an infection, or if you are feeling unwell or feverish. You may need to delay your treatment if you have an infection. Also let your IBD team know if you have often had infections in the past.
- You have HIV or hepatitis (a liver infection caused by a virus). You will usually have a blood test to check for these viruses.
- You have ever had chicken pox, shingles, cold sores or genital herpes. You may be able to be vaccinated against these before you start treatment.
- You have a condition or take any other medicine that weakens your immune system.

Your IBD team may also ask about any vaccinations you have had. This is to make sure that your vaccinations are up to date before you start filgotinib. Let them know if you are going to have any vaccinations, or you have had a vaccination recently.

Filgotinib may increase blood cholesterol levels in some people. Your IBD team will do a blood test to measure your cholesterol levels before you start treatment. They will measure the levels again after you have been taking filgotinib for about 12 weeks. You may need further checks or treatment to lower your cholesterol levels.

Filgotinib can reduce the levels of white blood cells (lymphocytes, neutrophils) and red blood cells (haemoglobin) in your blood. You should have blood tests before you start

treatment to check these. You should also have these levels checked at regular intervals during treatment. Depending on the results your IBD team may recommend that you delay or stop treatment with filgotinib. You will be able to start filgotinib again when the blood levels return to normal.

Ongoing checks

When you start filgotinib, your IBD team should advise you how and when they will review how well it is working. Your IBD team will ask about your symptoms and any side effects that you may be getting. Your IBD team will also check for any signs of infection.

You will have regular blood tests to check your white blood cells and red blood cells.

It's important that you attend your appointments and have blood checks to make sure this medicine is prescribed safely.

Special precautions

There are some things that might mean filgotinib is not right for you, or that it could have a higher risk of causing serious side effects.

The UK Medicines Agency (the MHRA) has recommended that all JAK inhibitors, including filgotinib, should only be used in the following people if no other suitable options are available:

- People aged 65 years or over
- People with an increased risk of having a heart attack or stroke
- People who smoke or have smoked in the past for a long time
- People who have an increased risk of getting cancer

The MHRA also recommends that these medicines should be used with caution in people who are **at risk of blood clots** in their lungs or legs.

If filgotinib is used in people with any of these risk factors, the **dose** should be reduced.

Risk of heart attack or stroke

An increase in the risk of heart attacks and stroke has been seen with tofacitinib (another JAK inhibitor) compared with anti-TNF medicines (such as infliximab and adalimumab). Heart attacks and stroke have also been seen in some people taking filgotinib. Because of this, filgotinib should only be used in people who are at higher risk of heart disease and stroke if no suitable option is available. Find out more about the risk factors for [heart disease and stroke](http://www.nhs.uk) (www.nhs.uk).

Seek urgent medical care if you experience any of the following during treatment:

- Chest pain or tightness, which may spread to arms, jaw, neck and back
- Shortness of breath
- Cold sweat
- Light headedness or sudden dizziness
- Weakness in arms or legs
- Slurred speech

Risk of cancer

An increase in the risk of some cancers has been seen with tofacitinib (another JAK inhibitor) compared with anti-TNF medicines (such as infliximab and adalimumab). Some cancers have also been reported in some people taking filgotinib. Because of this, filgotinib should only be used in people who are at higher risk of cancer if no suitable option is available.

Certain types of skin cancer ([non-melanoma skin cancer](#)) have been seen in people taking filgotinib. If you are at high risk of skin cancer your doctor may recommend that you have regular skin examinations.

To reduce your risk of skin cancer it is a good idea to:

- Go to any routine cancer screening you are invited to.
- Contact your GP if you notice any skin abnormality that persists for more than 4 weeks. This might be a lump, ulcer, skin discolouration or an area of skin that looks different to the skin around it.
- Protect your skin from the sun – use sunblock, cover your skin and wear a hat when you are out in the sun and do not use sun beds. The NHS has more information on [sun safety](#).

Blood clots

In some medicines that work in a similar way to filgotinib an increased risk of blood clots in the legs (deep vein thrombosis) or lungs (pulmonary embolism) has been seen. The risk of blood clots in people taking filgotinib is not yet known and is likely to be low. The risk is likely to be higher if you have other factors for blood clots. Risk factors include:

- Older age
- Obesity,
- Being a smoker,
- Having a blood clot in the leg or lung in the past,
- Having major surgery or
- Not being very mobile

Find out more about the risk factors for [blood clots](#).

- Tell your IBD team before you start taking filgotinib if you have had blood clots in your legs or lungs in the past.
- Seek urgent medical care if you get a painful swollen leg, pain in your chest or back, or shortness of breath while you are taking filgotinib.

Side effects

When you start taking filgotinib you should be given a Patient Alert Card. It is recommended that you carry this card with you. This is so that anyone treating you will know that you are taking filgotinib.

All medicines can have side effects, but not everyone will get them. Some side effects can happen right away, others may happen later. Some side effects are mild and may go away on their own, or after you stop taking filgotinib. Others may be more serious and could need treatment. Some side effects might mean that filgotinib is not right for you.

Speak to your IBD team if you experience any side effects.

Infections

Because filgotinib suppresses your immune system your body might not fight off infections as well as other people. You might get more infections than you are used to. Or if you get an infection, it might last longer or be more serious than usual.

Between 1 and 10 in every 100 people who take filgotinib might get a cold, sore throat, sinus infection or urine (wee) infection. Between 1 and 10 in every 1000 people who take filgotinib might get a more serious infection such as pneumonia or shingles.

Talk to your doctor or get medical help straight away if you get any signs of serious infection such as:

- A high temperature, shortness of breath, a cough that will not go away or feeling more tired than usual. These may be signs of pneumonia.
- A high temperature, sweating, weight loss or a cough that will not go away. These may be signs of tuberculosis (TB).
- Needing to wee more often than usual, or a burning or stinging feeling when you wee. These may be signs of a urine infection.
- A painful skin rash with blisters. This may be a sign of shingles.

If you get an infection, your IBD team might tell you to stop taking filgotinib while the infection is treated. You should be able to start filgotinib again when the infection is under control.

Common side effects

The most common side effects of filgotinib are listed below. These affect between 1 and 10 in every 100 people who take filgotinib.

- Common cold, sore throat or sinus infection.
- Urine infection.
- Feeling sick (nausea). This will usually go away if you keep taking filgotinib. Taking filgotinib with food may help.
- Feeling dizzy. This will usually go away if you keep taking filgotinib. If you do feel dizzy, do not drive and do not use any tools or machines

This is not a full list of side effects. For more information see the Patient Information Leaflet provided with your medicine or visit [medicines.org.uk/emc/](https://www.medicines.org.uk/emc/).

The safety of any new medicine will continue to be monitored after it has become available for use. This is done through longer term clinical studies and through reporting of side effects. We encourage you to report any side effects to the Medicines and Healthcare Products Regulatory Agency (MHRA). You can do this through the [Yellow Card scheme online](https://www.mhra.gov.uk/yellowcard) or by downloading the MHRA Yellow Card app ([yellowcard.mhra.gov.uk](https://www.mhra.gov.uk/yellowcard)). This helps collect important safety information about medicines.

Taking other medicines

If you take filgotinib with other medicines that affect your immune system you may be at increased risk of severe infection. Tell your IBD team, doctor or pharmacist if you take other medicines that affect your immune system. You may take these for other medical conditions.

Some medicines can affect how filgotinib works. These include:

- Some medicines to treat heart failure, coronary disease or high blood pressure, such as diltiazem or carvedilol.
- Some medicines used to treat high cholesterol, such as fenofibrate or simvastatin.

Speak to your IBD team, doctor or pharmacist if you are taking or plan to take any other medicines while you are taking filgotinib. This includes medicines that you buy from a pharmacy or a supermarket. It also includes any herbal, complementary or alternative medicines.

Drinking alcohol

Alcohol is not known to interact with filgotinib. To keep the health risks from drinking alcohol low it is best to stay within the [recommended limits](#).

Vaccinations

Your IBD team will check that your vaccinations are up to date before you start treatment with filgotinib. This may include the shingles vaccine and BCG.

You should not have live vaccines while taking filgotinib.

- If you have had a live vaccine you should wait for at least 4 weeks before starting filgotinib.
- You should not have a live vaccine until at least 3 months after your last dose of filgotinib.

In the UK, live vaccines include:

- Rotavirus vaccine.
- Measles, mumps and rubella (MMR) vaccine.
- Nasal flu vaccine used in children: the injected flu vaccine used in adults is **not** live.
- Shingles vaccine: a non-live vaccine is also available for people with severe immunosuppression.
- Chickenpox vaccine.
- BCG vaccine against TB.
- Yellow fever vaccine.
- Oral typhoid vaccine: but the injected typhoid vaccine is **not** live.

If someone you live with is due to have a live vaccine, ask your IBD team if you need to take any precautions.

The flu, pneumococcal and COVID-19 vaccines are not live vaccines and are safe to have while you are taking filgotinib.

Pregnancy and fertility

Animal studies have suggested that filgotinib may affect sperm production and sperm quality. But results from a recent study in humans did not show any difference between filgotinib and dummy treatment (placebo).

There is no evidence that filgotinib affects fertility in people who can get pregnant.

You should not take filgotinib if you are pregnant or are planning to become pregnant. Let your IBD team know immediately if you are taking filgotinib and you become pregnant or you think you might be pregnant. They will be able to discuss the next steps with you.

There is very little information about the use of filgotinib in pregnancy. But studies in animals suggest that it may cause harm to the unborn baby. Use effective contraception whilst you are taking this medicine and for at least 1 week after you stop taking it if you could get pregnant.

Our information on [Reproductive Health](#) can help you decide on the right contraceptive for you.

If you are planning to get pregnant, speak with your IBD team as soon as possible. This will allow time to review your treatment options and make sure your Colitis is controlled as well as possible.

Breastfeeding

We do not know if filgotinib passes into breast milk or what effect it would have on a baby that is breastfeeding. You should not take filgotinib if you are breastfeeding.

Who to talk to if you are worried

Taking medicines and managing side effects can be difficult – we understand and we're here to help. Our [Helpline](#) can answer general questions about treatment options and can help you find support from others with the conditions.

Your IBD team are also there to help. You can talk to them about your dosage, how they'll be monitoring you and what alternatives may be available. You should also get in touch with your IBD team if you have any new symptoms or side effects.

It can take time to find the medicine that's right for you. Don't be afraid to ask questions and seek out extra support when you need it.

This information is general and doesn't replace specific advice from your health professional. Talk to your doctor or IBD team for more information.

Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our award-winning information on Crohn's Disease, Ulcerative Colitis, and other forms of Inflammatory Bowel Disease 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 and employment. We'll help you find answers, access support and take control.

All information is available on our website: crohnsandcolitis.org.uk/information

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
- Help you understand and access disability benefits
- Be there to listen if you need someone to talk to
- Help you to find support from others living with the condition

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

Members of Crohn's & Colitis UK get benefits including a Can't Wait Card and a RADAR key to unlock accessible toilets. This card shows that you have a medical condition, and will help when you need urgent access to the toilet when you are out. See crohnsandcolitis.org.uk/membership for more information, or call the Membership Team on **01727 734465**.

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not intended to replace advice from your own doctor or other professional. We do not endorse any products mentioned.

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 information 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.

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We hope that you've found this information helpful. You can email the Knowledge and Information Team at evidence@crohnsandcolitis.org.uk if:

- You have any comments or suggestions for improvements
- You would like more information about the research on which the information is based
- You would like details of any conflicts of interest

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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