

Infliximab

Infliximab is a common treatment for people with **Crohn's** and **Colitis**.

Our information can help you to decide if this treatment is right for you. It looks at:

- How the medicine works
- What you can expect from the treatment
- Possible side effects
- Stopping or changing treatment

This information should not replace advice from your health professional. Talk to your IBD team or read the leaflet that comes with your medicine for more details. You can also find out about your medicine at medicines.org.uk.

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Key facts about infliximab

- Infliximab is used to treat <u>Crohn's</u> and <u>Colitis</u> in adults. It can also be given to children who are six years old or over. Infliximab doesn't work for everyone.
- You'll first take infliximab through a drip into a vein in your arm. This is known as intravenous infusion. After this, adults may take it by infusion or by injection under the skin. This is known as a subcutaneous injection.
- Infliximab affects the way your immune system works. This means you may be more at risk of infections. You may be advised to do extra things to protect yourself.
- Tell your IBD Team if you notice any side effects, or if you have signs of an infection.
- You should not have any live vaccines while taking infliximab. Having annual flu and COVID-19 vaccinations can help protect you. These are safe to take because they are not live vaccines.



 Infliximab is generally considered safe to take during pregnancy. You should talk to your IBD team if you are thinking of having a baby.

Other names for this medicine

Infliximab for infusion is known by several brand names, including:

- Flixabi
- Inflectra
- Remicade
- Remsima
- Zessly

The brand name for infliximab for subcutaneous injection is Remsima. A subcutaneous injection is an injection given into the fatty tissue just under the skin. This medicine is prescribed by brand name.

Remicade was the first brand of infliximab. Flixabi, Inflectra, Remsima and Zessly work in the same way but are known as 'biosimilars'. This means they are very similar to Remicade and have the same treatment effects. But there are some slight differences, such as different ingredients to give them a longer shelf-life. The brand that you are given won't affect your treatment, but you may want to ask your healthcare professional which brand you take. For more about biosimilars see our information on **biologic medicines**.

I've been having infliximab treatment for over 5 years, having suffered with UC for over 35 years with regular flare-ups. The treatment has enabled me to live a normal life without the need to take lots of tablets.

Claire



Living with Ulcerative Colitis

What infliximab is and how it works

Infliximab belongs to a group of medicines called <u>biologic medicines</u>. Biologic medicines are made by a biological rather than a chemical process. They're produced in a lab by living cells.

Infliximab is an antibody-based medicine. It targets a protein in the body called tumour necrosis factor-alpha (TNF-alpha). TNF-alpha is naturally produced by your body and helps fight off infections. Too much TNF-alpha can damage the cells that line the gut. This may partly be the cause of gut inflammation for people with Crohn's or Colitis. Infliximab binds to TNF-alpha, blocking its harmful effects, which reduces inflammation. This can help to relieve symptoms.

Infliximab is sometimes called an 'anti-TNF' medicine. Other anti-TNF medicines are:

- Adalimumab (used to treat Crohn's and Colitis)
- Golimumab (used to treat Colitis)

Why you've been offered infliximab

Infliximab is used to treat adults and children from 6 years of age with:

- Moderately to severely active Crohn's
- Moderately to severely active Ulcerative Colitis

It may be given to you if other treatments, such as <u>steroids</u>, <u>azathioprine</u>, <u>mercaptopurine</u> or <u>methotrexate</u>:

- Have not worked or have stopped working
- Have caused significant side effects
- Are not suitable for you



Infliximab is also used to treat active fistulas in adults with Crohn's if other treatments have not worked. Find out more in our information on <u>living with a fistula</u>.

The aim of using this medicine is to try to get your condition under control and keep it under control. This is known as being in remission. Remission is when you feel better because your Crohn's or Colitis is being controlled well. During this time, medical tests, such as blood tests and endoscopy, show your gut is less affected. Your symptoms, such as diarrhoea, abdominal pain or fatigue will improve. However, some symptoms, like fatigue, may not go away completely. Keeping your Crohn's or Colitis under control is good for your long-term health. It lowers your risk of complications and need for surgery.

Current guidelines suggest using Infliximab if other medicines have not worked. A 2024 study found that using infliximab soon after diagnosis reduced the need for surgery and helped keep people in remission in the first year. Some healthcare professionals may consider using this approach. Others may think it best to stick to current guidelines while the impact of this research is reviewed.

Acute Severe Ulcerative Colitis (ASUC)

If you are seriously unwell in hospital with Ulcerative Colitis, you may be given 'rescue therapy'. This is an emergency treatment to try to prevent unplanned surgery. For some people, this will include infliximab.

Other health conditions

Infliximab is also to treat psoriasis and certain types of arthritis.

Deciding which medicine to take

You may have been given a choice of taking infliximab or another biologic medicine. Our information on <u>medicines for Crohn's and Colitis</u> can help you decide.

There are lots of things to think about when you start a new medicine. Your IBD team will talk to you about your options. For new medicines, you might want to think about the aim



of the treatment and what the pros and cons might be. Some things to think about include:

- How you take it
- How well it works
- How quickly it works
- Possible side effects
- Whether you need ongoing tests or checks
- Other medicines you are taking
- What happens if you don't take it

Our <u>medicines tool</u> can help you understand more about the potential treatment options that suit your needs.

Our <u>Appointment guide</u> has a list of questions you might want to ask your healthcare professional. It can help you focus on what matters most to you. We also have information on other <u>medicines</u> or <u>surgery</u> for Crohn's or Colitis.

How effective infliximab is in Crohn's and Colitis

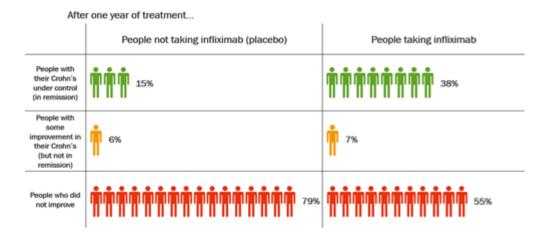
Infliximab can help to get your Crohn's or Colitis under control and keep it under control.

Find out more about how we talk about the **effectiveness of medicines**.

If you have Crohn's Disease

The table below shows data from clinical trials of infliximab in adults with moderate to severely active Crohn's.

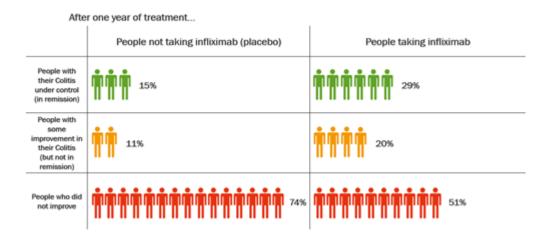




More than twice as many people had their Crohn's under control after taking infliximab for one year compared with people who had not been taking infliximab. But infliximab does not work well for everyone with Crohn's Disease.

If you have Ulcerative Colitis

The table below shows data from clinical trials of infliximab in adults with moderate to severely active Colitis.



Twice as many people had their Colitis under control after taking infliximab for one year compared with people who had not been taking it. But infliximab does not work well for everyone with Ulcerative Colitis.

My main concern with starting infliximab was the safety of the drug, both in the short and long term.



Knowing that it had undergone rigorous clinical trials helped give me the confidence to go ahead with it. Five years on it's still allowing me to enjoy a normal quality of life.

Rebecca

Living with Crohn's Disease

How quickly infliximab works

Everyone responds differently when taking a new medicine. You may feel better soon after starting treatment. It may take two or three doses before you feel better.

Infliximab does not work for everyone. Your IBD specialist will check how well it is working for you.

How to take infliximab

Infliximab can only be prescribed by a specialist in a hospital. Your GP cannot prescribe it for you to pick up from your local pharmacy. You won't have to pay for your infliximab prescription if you are entitled to NHS care. This includes if you normally live in the UK legally or you are returning to live in the UK and you are not a visitor. The Citizens Advice has <u>more information</u> about access to free NHS care.

Infliximab cannot be taken by mouth. It is usually given through a drip into a vein in your arm. This is called an intravenous infusion.

Some hospitals may offer the option to take infliximab by injection. This will only be available to adults. To do this, you can use a pre-filled pen or syringe that you inject yourself under your skin.

• For the syringe, you insert the needle and press the plunger down yourself.



 For the pen, you position it and press a button, which inserts the needle and injects the medicine for you.

Even if you take infliximab by injection, you'll first need to have two doses by infusion in hospital. Infusions and injections are equally effective in treating Crohn's and Colitis. Ask your IBD team how you will be taking it.

How to take infliximab by infusion

Infliximab infusions are usually given in hospital by a trained member of staff. You'll be treated as a day patient unless you are already in hospital. Before your infusion, you'll be asked:

- About your general health
- If you've had any new symptoms
- If you have any signs of infection

You'll have the infusion while sitting in a chair or on a bed. You won't have to undress, get into bed or stay the night. Infliximab will flow from a bag through a tube into your arm or hand. Blood samples may be taken for tests.

To help prepare for an infusion you could:

- Wear loose and comfy clothing. This may make it easier for you to have your infusion. Loose clothing can also keep you comfortable while you wait.
- Stay hydrated for when you have your infusion. Always follow any advice you are given about when to eat or drink before having an infusion.

Your first infusion usually takes about two hours. Afterward, your healthcare team may check how you are. This can take one to two hours. You may need to set aside at least half a day for your first visit. Your next infusions may be given faster depending on the practice at your clinic. Some people may only be in the hospital for about two hours if they've been a few times.



Your medical team will monitor you during and after your infusion. This is to check that you do not develop an allergic reaction. Your medical team may give your infusion at a slower rate if you've had an allergic reaction before. This can reduce your risk of another reaction. You may be given paracetamol, antihistamine or hydrocortisone just before the infusion. This can reduce the risk of side effects.

You may be able to fit your infusion sessions around other activities in your day. Some people go straight to work after their infusion. Other people may prefer to go home. When you have your first infusion, you may want to arrange for someone to pick you up. Having an infliximab infusion shouldn't affect your ability to drive. But do not drive if you feel tired, dizzy or unwell.

When I was doing my PhD, whilst getting my infusions, I worked on chapters, and did some reading, editing and proof-reading of my text. This helped with seeing myself not just as a patient but also as a human being who could still do things despite being linked up to a machine!

Gillian

Living with Crohn's

Dosage information for infusions

For an infusion, you'll be given 5mg of infliximab for every kilogram you weigh. This dose is the same for both adults and children. The hospital will work out how much you need and will make up the infusion for you.

After your first infusion, you'll have a second one two weeks later. You'll have a third infusion four weeks after that. If you respond well, you'll be put on maintenance dosing of an infusion every eight weeks.



If infliximab doesn't work for you, or it becomes less effective, your doctor may suggest changing things. This may include trying a higher dose and may be based on how well infliximab is working for you. Speak to your IBD team if you think this treatment is not working as it should.

Continue every 8 weeks Week Week Week 0 Week 2 Week 6 14 22 5mg/kg 5mg/kg 5mg/kg 5mg/kg 5mg/kg Infusion Infusion Infusion Infusion Infusion in in in in hospital hospital hospital hospital hospital

Infusion dosing schedule in adults and children

How to take infliximab by injection

Induction doses

Only adults can take infliximab by injection. Even if you will be taking infliximab by injection, you'll have your first two doses by infusion in hospital. See the previous sections on infusions.

Maintenance doses

You'll usually have your first injection in hospital or by a trained nurse at home. You'll then be trained to inject it yourself. If you prefer, it may be possible for someone else, such as a family member, to be trained to give your injections.

Infliximab comes ready to use in either a pre-filled syringe or a pre-filled injection 'pen'. For the injection pen, the needle is inside the device and may not be seen. The syringes or pens come in a pack. Each pack contains an alcohol pad to clean your skin before you inject.



Delivery

Infliximab will usually be sent directly to your home by a special delivery company.

Storage

Keep infliximab injections in the fridge, between 2°C and 8°C. They should be kept in their original carton to protect them from light.

You can also store these injections out of the fridge at temperatures up to 25 °C, but only for up 28 days. This might be useful if you are travelling. These injections must be kept out of direct sunlight. If kept out of the fridge, they must be kept in their original carton. Do not use the injections if they are left out of the fridge for more than 28 days. Ask your pharmacist to get rid of any you haven't used. Find out more about travelling with medicines.

Tips on injecting

Make sure you know how your injection device works.

Pain at the injection site is a common side effect. You may also get redness, itching and swelling. These tips might help to make the pain easier to manage:

• Let your medicine warm to room temperature

Injecting yourself with infliximab straight from the fridge may feel uncomfortable. Try taking it out of the fridge about 30 minutes before you inject it. This helps it warm to room temperature. Do not warm the injection in any other way. For example, do not put it in hot water or use a microwave.

Choose your injection site

Good places to inject are the upper thigh and stomach. If you inject it into your stomach, choose somewhere at least 5cm away from your belly button. Avoid any areas where the skin is red, scarred, bruised or hard. Use an area at least 3cm away from other sites. Injecting too close to a recent site may cause a hard lump to form.

Try using an ice pack before you inject



Before you inject, put an ice pack on the area for two to three minutes. This can help to numb the area before you inject. Put a damp towel under the ice pack or wrap it in a damp cloth. This can stop your skin being damaged by the cold.

Wash your hands and clean the skin at the injection site
 Wash your hands with soap and water. Clean the skin with an alcohol wipe before
 you inject yourself. This can reduce the risk of infection.

• Use a good injection technique

For the pre-filled syringe, use one quick motion to insert the needle into your pinched skin. Push the plunger slowly and evenly to inject all the medicine. Keep pressure on the plunger head and keep your skin pinched. This will take about two to five seconds.

For the pre-filled pen, first remove the cap. Place the pen on the injection site at a 90° angle. Make sure you can see the window on the pen. Do not pinch or stretch the skin. Press the pen firmly onto the skin. When the injection starts, you'll hear a click. After you hear a second click, continue to hold the pen down for the count of five.

Wear loose clothing

Wear loose clothing to avoid rubbing or pressure on the injection site.

If you still have problems with injecting, ask your IBD team for help.

Dosage information for injections

Your first dose will be given by infusion in hospital. You'll also have another infusion in hospital two weeks later. You'll be given 5mg of infliximab for every kilogram you weigh. The hospital will work out how much you need and make up the infusion for you. These are called induction doses. See the section on **How to take infliximab by infusion**.

If you respond well, you can change to dosing by injection. You'll have your first 120mg injection four weeks after your second infusion. You'll then have a 120mg injection every two weeks. These are called maintenance doses.



If infliximab doesn't work for you, or it becomes less effective, your doctor may suggest some changes to your dosing schedule. These changes may depend on your symptoms, blood test results and the levels of medicine in your blood. Speak to your IBD team if you think this treatment is not working as well as it should. You must not make any dose changes unless your IBD team tell you to.

Injection dosing schedule (adults only)

		C	Continue every 2 week	
Week 0	Week 2	Week 6	Week 8	Week
Week O	Week 2	Week o	Week o	10
5mg/kg	5mg/kg	120mg	120mg	120mg
		Injection		
Infusion	Infusion	in	Self-	Self-
in	in	hospital	inject at	inject at
hospital	hospital	or nurse	home	home
	'	at home		
Inc	duction doses		Maintenance doses	·

How long will I be on infliximab?

If infliximab works well, you'll continue your treatment for at least one year. After that, your IBD team will check that this medicine still helps. If it does, you will most likely continue treatment. If you continue treatment, your IBD team should assess you at least every 12 months. This is to make sure infliximab is still right for you.

Stopping or changing treatment

Your IBD team may think it is right to stop or change your treatment if:

 Infliximab is not effective. Your IBD team will give your medicine 6-14 weeks to work. They may stop treatment if it hasn't worked for you in this time. This will



depend on your condition and the practice at your hospital. Your IBD team may check the levels of the medicine in your blood. They may try changing your dose before stopping treatment.

- Your Crohn's or Colitis is under control. You may be able to stop your medicine if
 your condition is under control for 12 months. If you become unwell again, you
 should be able to restart infliximab. Re-starting anti-TNF treatments is successful
 in nearly nine in ten people (88%) with Crohn's, and three in four people (76%)
 with Colitis.
- You have side effects. You may need to stop taking infliximab if you have side effects and they are:
 - Serious
 - Affect your daily life
 - o Hard to manage.
- Infliximab becomes less effective. Over time, some people develop antibodies to
 infliximab. This can stop it working. Your antibody levels will be checked using a
 blood test. You may need to have this blood test before each dose of infliximab.

You have a right to take part in decisions about your treatment. Tell your IBD team what matters most to you. This will help them give you the information and support you need. Our **guide to appointments** can help you have these conversations. Do not stop taking your medicine unless your IBD team say it is ok. If you must stop taking this medicine, but are still unwell, you may be able to try a different biologic. See our information on **biologic medicines**.

Taking infliximab with other Crohn's or Colitis treatments

You may take infliximab with some other medicines for your Crohn's or Colitis. These include:

- <u>5-ASAs</u> (like mesalazine)
- Thiopurines, such as azathioprine or mercaptopurine



Methotrexate.

Taking more than one medicine is known as combination therapy. For more on this, see our information on <u>taking medicines</u>.

Taking a combination of infliximab with methotrexate or a thiopurine, such as azathioprine, may be more effective. This can reduce the risk of treatment becoming less effective over time. Speak to your IBD team about the risk of side effects with combination therapy. You should decide together what the best treatment option is for you.

Checks before starting this medicine

Your IBD team will check if infliximab is right for you. This may include blood tests and imaging.

Medicines that affect your immune system can make it more difficult to fight off infections. Before you start infliximab, your IBD team may ask you some questions and do some tests.

Tell your IBD team if you have a history of:

- Tuberculosis, known as TB. Tell your IBD team if you have recently been close to someone who has it. You should not be given this medicine if you have active TB. If you have underlying, inactive TB, this will need to be treated first. You'll usually have a chest X-ray to check for TB.
- Infections. This includes any past or current infections, even if it is a small one. Your IBD team may check you are not generally feeling unwell or feverish. You may need to delay your treatment if you have an infection.
- HIV or hepatitis. This includes any past or current infections. Hepatitis is a liver
 infection caused by a virus. You will need to tell your IBD team if you:
 - Have hepatitis
 - Are a carrier and don't have any symptoms.



Have been in close contact with someone who has hepatitis.

You will have a blood test to check for these diseases.

- Heart problems. If you do, your heart will be monitored closely before, during, and after treatment. In rare cases, it could make your heart problems worse.
- Cancer. Infliximab affects how your immune system works. This may increase the
 risk of some types of cancer. This may include lymphoma. You may also be at risk
 even if you do not have a history of cancer.
- **Pre-existing conditions.** These include:
 - Allergies
 - COPD (Chronic Obstructive Pulmonary Disease)
 - o Asthma
 - Kidney disease
 - Liver disease
 - Low blood count
 - o Lupus
 - o Guillain-Barre syndrome
 - Multiple sclerosis
 - Any other disease or symptoms affecting the nervous system

And tell your IBD team if:

- You smoke
- You are pregnant, planning to get pregnant or are breastfeeding
- You have any fistulas
- You are taking any other medicines
- You have had any vaccinations recently, or plan to have any in the future
- You have had surgery, or plan to have surgery or dental treatment
- You have travelled or are planning on travelling to regions of the world where you may have a higher risk of:
 - o TB



- Fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis
- You have ever had chicken pox, shingles or measles. If you have not had these, you may be able to be vaccinated against them.

Ongoing checks

You'll need regular checks while taking infliximab. This may include blood tests. This helps your IBD team to make sure your treatment is working well. Regular checks can catch problems at an early stage. Tell your IBD team if you notice any new symptoms or side effects.

Blood tests may be used to check the levels of infliximab and antibodies in your blood. This helps your IBD team to see if infliximab is working or if your dose needs changing.

You need to attend your appointments and have blood tests so that your infliximab is given to you safely.

Special precautions

Infliximab is unlikely to affect if you can drive. If you do not feel well after an infusion, you should not drive. If you are having your first dose of infliximab and are unsure how you'll feel, arrange for a taxi or ask someone to drive you home.

This medicine affects the way your <u>immune system works</u>. Your immune system is still able to fight off infections, just not quite as well as other people's. You may find that infections affect you more than they used to. It may also take you longer to recover. Tell your IBD team if you have signs of an infection. This might include a sore throat, fever or any new symptoms that concern you. They may advise you to wait until you feel better before having infliximab. Less often, more serious infections can be a side effect of infliximab. See the section below on **side effects**.

Although your risk of infections may be higher when taking infliximab, it should not stop you from living life as before. There are a few extra precautions your IBD team may



recommend that you take. These can help to keep you safe and reduce your risk of illness:

- Have annual vaccinations. Annual flu and COVID-19 vaccinations may help protect
 you. You may also be advised to have a pneumococcal vaccine. This can help
 protect you against serious illnesses like pneumonia and meningitis. Ask your IBD
 team if you need to have this just once, or every five years.
- Avoid close contact with people who have serious infections. This includes:
 - Chickenpox
 - o Shingles
 - Measles
 - o TB
 - Pneumococcal disease.

Tell your IBD team if you come into contact with anyone with these conditions, even if you don't feel unwell.

- Practice good hand washing hygiene. Wash your hands regularly with soap and
 water or use an alcohol-based hand gel. Take extra care to do this before eating
 and after using public transport. Try to avoid touching your face when your hands
 are not clean.
- **Practice good food hygiene.** You may be at risk of more severe infections caused by bacteria found in food. These include *Listeria* or *Salmonella*. Avoid eating:
 - o Raw eggs
 - Undercooked pate
 - Undercooked meat
 - Undercooked poultry.

You should also avoid unpasteurised milk or cheeses. Nearly all dairy sold in UK supermarkets is pasteurised and safe to eat. This includes soft and 'blue' cheeses. Always check the label if you are unsure. Ask whether unpasteurised milk was used when buying soft cheese from farmers' markets or abroad.

• Take care in the sun. You may be more at risk of skin reactions, and in rare cases skin cancer. Taking azathioprine or mercaptopurine with infliximab can increase this risk. Practice good sun safety. This includes wearing a hat and high-factor



sunscreen, staying in the shade and avoiding sunbeds. The <u>NHS website</u> has more tips for staying safe in the sun.

• Attend routine screening for cervical cancer if appropriate to you. Cervical cancer screening was previously known as the smear test. Changes to the cells in the cervix can be caused by the human papilloma virus (HPV). If you are immunosuppressed, you are more likely to have these changes. There's no need to be tested more regularly than other people. All women and people with a cervix between the ages of 25 and 64 should go for regular cervical screening. You will get a letter from your GP surgery inviting you to make an appointment.

You can find out about other things you can do to look after yourself on our Immunosuppressant precautions page.

I try to avoid people with infections, where possible.

When I'm in the sun, I cover my arms and legs because I know my skin is more sensitive with taking infliximab.

Jean

Living with Crohn's

Side effects

All medicines can have side effects, but not everyone gets them. Having certain side effects might mean that infliximab is not right for you.

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

- Some side effects can happen right away. Others may happen after you have been taking infliximab for a while.
- Some side effects are mild. Others may be more serious and could need treatment.



 Some side effects may go away on their own. Others may go away after you stop taking infliximab. Some may be long lasting.

Possible serious side effects

Some people might get serious side effects that need urgent treatment. These do not happen often, but it is important to know what to look out for.

Allergic reactions

Some people taking infliximab might have an allergic reaction. Severe allergic reactions are uncommon. Life-threatening reactions are rare.

Contact NHS 111 or call 999 straight away if you think you are having an allergic reaction.

Signs to look out for include:

- Difficulty breathing or swallowing
- A rash or raised, itchy patches on your skin, known as hives
- Swelling of your face, lips, mouth or throat
- Swelling of the hands, feet or ankles
- Feeling dizzy or light-headed
- Your heart starts beating very fast

After an allergic reaction has been treated, contact your IBD team to let them know what happened.

Infections

If you take infliximab, you may get infections more easily. This is because infliximab can affect your immune system. You might get more infections than you are used to. Infections might last longer or be more serious than usual. Sometimes, previous infections can reappear, such as tuberculosis or hepatitis B virus.



Tell your doctor or IBD team immediately if you develop:

Symptoms of an infection. The list below are symptoms to watch out for in yourself and in others:

- Flu-like symptoms, feeling feverish or generally unwell
- Feeling overly tired
- · A persistent cough with mucus or phlegm
- Shortness of breath
- Diarrhoea
- Warm painful skin
- Stinging when passing urine
- Swelling or pain around a cut or a wound
- Tooth or gum pain or swelling
- Puss in the gut or around the opening to your bottom

Most common side effects

Around 1 in every 10 people taking infliximab may have:

- Infusion or injection site-related reactions. This might include redness, swelling or pain where you've injected
- Flu or upper respiratory tract infections, such as colds, tonsillitis and sinus infections
- Tummy pain or feeling sick
- Headaches

Other side effects

- Gut problems. Some of these will be similar to the symptoms of Crohn's or Colitis.
 Speak to your IBD team if you are not sure what may be causing your symptoms.
 - o Common: Diarrhoea, reflux, indigestion or constipation.
- Changes in your mental health.
 - Common: Depression or trouble sleeping.
 - Uncommon: Confusion, memory loss or feeling agitated.



- Nervous system problems.
 - Common: Dizziness or vertigo. Vertigo is feeling like you or everything around you is spinning.
 - o Uncommon: seizures, known as fits.
 - o Rare: Demyelination disorders damage to nerves.
- Blood problems. Tell your doctor straight away if you have a fever that does not go
 away. Tell them if you are bruising or bleeding very easily, have a sore throat, or
 look pale.
 - Common: Low iron levels, your body may not make enough of the blood cells that help fight infections.
 - Uncommon: Your body may not make enough of the blood cells that help to stop bleeding.
- Heart problems. Tell your doctor straight away if you have new or worsening shortness of breath, swelling of your ankles or feet, or sudden weight gain.
 - Common: Increased heart rate or feeling like your heart is pounding or fluttering.
 - Uncommon: New or worsening heart failure.
- Liver problems. Tell your doctor if your skin or eyes look yellow. You should also tell them if you feel very tired with a lack of appetite, or you have an ongoing pain on the right-hand side of your tummy.
 - Common: Abnormal liver function tests.
 - Uncommon: Infliximab can activate viral hepatitis if you carry it in your blood. Your doctor will check if you are a carrier before you start treatment.
 They will use blood tests to check it does not activate.
- **Skin reactions.** Some of these can be treated without stopping infliximab.
 - o Common: Scaly patches on your skin, eczema, other skin rashes, dry skin.
 - Uncommon: Ulcers or warts.
- Some types of skin cancer. You must tell your doctor if you have a bump or open sore that is not healing.
 - o Rare: Melanoma.



- Other types of cancer. This medicine may not be right for you if you have previously had cancer.
 - Rare: Lymphoma, cervical cancer or leukaemia.
 - Not known: A rare and serious cancer called hepatosplenic T-cell lymphoma (HSTCL). HSTCL has been found in some people taking anti-TNF medicines with azathioprine or mercaptopurine. Most cases have been in males with Crohn's under the age of 35. The risk hasn't been measured – but it is a rare cancer, and rarer still in people taking these medicines.

How common are these side effects?

Common	somewhere between 1 in every 10 people to 1 in every 100 people		
	taking infliximab may develop this side effect.		
Uncommon	somewhere between 1 in every 100 people to 1 in every 1000 people		
	taking infliximab may develop this side effect.		
Rare	somewhere between 1 in every 1000 people to 1 in every 10,000		
	people taking infliximab may develop this side effect.		

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/.

We encourage you to report any side effects to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card scheme. Your doctor should also report it. You can report your side effect at yellowcard.mhra.gov.uk.

Taking other medicines

Infliximab is often taken alongside other medicines safely. See the earlier section <u>Taking</u> infliximab with other Crohn's or Colitis treatments.

However, infliximab may interact with other medicines. Speak to your doctor or pharmacist if you are taking, or plan to take any other medicines. This includes:

- Medicines that you can buy over the counter
- Any herbal, complementary, or alternative medicines or therapies



Do not take medicines that contain anakinra or abatacept. These medicines are commonly used for rheumatoid arthritis.

Telling other health professionals

When starting infliximab, you should be given a patient reminder card, also known as a patient alert card. This contains important safety information about infliximab. You should show this card to any doctor, dentist or healthcare professional that is treating you. Always carry this card with you while you are taking infliximab. You should also carry it for up to four months after your last dose. If you become pregnant, the manufacturers suggest keeping this card with you for 12 months after your baby is born.

Vaccinations

Live vaccines contain weakened live strains of viruses or bacteria. You should not have live vaccines if you are immunosuppressed. This is because the weakened virus could reproduce too much and cause a serious infection.

You should not have live vaccines while taking infliximab.

- If you have had a live vaccine, you may need to wait four weeks before starting infliximab.
- It can take up to six months after your last dose for infliximab to completely leave your body. However, it may be safe to have live vaccines three months after your last dose of infliximab. You may be advised to wait longer.

Ask your IBD team to make sure your vaccinations are up to date before you start infliximab. Talk to your IBD team if you are planning to travel and need vaccinations.

In the UK, live vaccines include:

- BCG (tuberculosis)
- Chicken pox (varicella)
- Measles, mumps and rubella either as individual vaccines or as the triple MMR vaccine
- Yellow fever



- Rotavirus babies only
- Nasal flu vaccine used in children the injected flu vaccine used in adults is not live
- Shingles vaccine (Zostavax) a non-live shingles vaccine (Shingrix) is available for people with severe immunosuppression
- Oral typhoid vaccine. The injected typhoid is not live

If someone that you live with is due to have a live vaccine

There is a small risk that people who have recently had a live vaccine could pass on the virus to close contacts who are immunosuppressed. This could then cause an infection.

For most of the live vaccines used in the UK, the virus is not passed on to contacts. You can reduce the risk by following simple precautions, such as:

- Wash your hands after direct contact with a person who has had the vaccine, and before preparing food.
- If the contact develops a rash after the live shingles vaccine, they should cover the rash until it is dry and crusted.
- Talk to your IBD team if someone you live with is due to have a live vaccine and you have any concerns.

Non-live vaccines

The annual flu vaccine, pneumococcal vaccine and COVID-19 vaccines are not live vaccines. They are safe to have while you are taking infliximab.

Everyone with Crohn's or Colitis taking a biologic medicine should have the yearly flu vaccine and COVID-19 vaccine. Flu vaccinations and COVID-19 vaccinations may not work as well in people taking infliximab.

Pregnancy and fertility



Fertility

Infliximab is not thought to affect male or female fertility.

Planning a pregnancy

Speak to your IBD team if you are offered or are taking infliximab and want to start a family. They can help you make an informed decision about your care and your baby's safety.

Do not stop taking your medicine without talking to your doctor first.

Stopping your medicine may increase your risk of a flare-up. Having active Crohn's or Colitis can increase the risk of pregnancy complications, such as:

- Premature birth
- Low birth weight
- Miscarriage

This is why it is important to keep your condition under control during pregnancy.

Infliximab is generally considered safe to take during pregnancy. Research shows that it is unlikely to affect your pregnancy or harm an unborn baby. Long-term health, infection rates and development do not appear to be affected in children with a parent who took anti-TNFs, like infliximab, during pregnancy.

It is possible for infliximab to cross the placenta and enter your baby's blood. This may happen in mid to late pregnancy, during the late second and third trimester. To be cautious, drug companies advise using contraception to prevent pregnancy while taking infliximab and for at least six months after your last dose. They also suggest that infliximab should only be used during pregnancy if needed to keep your condition under control.

However, many people will be advised by their healthcare professionals to continue taking infliximab throughout their pregnancy. This can help manage their condition effectively and reduce flare-ups. Flare-ups can increase the risk of pregnancy complications.



If your Crohn's or Colitis is well controlled, your IBD team may advise that you take infliximab for the first six months of your pregnancy only. This aims to reduce the exposure of your baby. If your condition is not well controlled, your IBD team may recommend you take infliximab throughout your pregnancy.

If you have an unplanned pregnancy

Contact your IBD team straight away if you are on infliximab and find out that you are pregnant. Do not stop taking your medicine until you have spoken to your healthcare professional.

Your baby and live vaccines

Tell your baby's healthcare team if you were taking infliximab during your pregnancy. Taking infliximab during pregnancy may affect when your baby can have live vaccines. This includes the rotavirus vaccine and the BCG vaccine for tuberculosis. The BCG vaccine is not routinely given as part of the NHS vaccination schedule but is sometimes recommended. Taking infliximab during pregnancy should not affect the rest of your baby's vaccination schedule.

If you take infliximab during pregnancy, you may be told that your baby should not have live vaccines until they're a bit older. National guidelines state that you may need to wait until your baby is between six and 12 months old or until infliximab can not be found in the baby's blood. The manufacturers of infliximab recommend to wait until at least 12 months old. But sometimes the benefit of giving a live vaccine earlier might be greater than the potential risk.

You might want to discuss this with your IBD team and your baby's healthcare team. Decisions on what vaccines your baby should have and when will be made on an individual basis. Your IBD team and midwife or baby's healthcare team should be able to help you make a decision.

If you take infliximab, you should take extra care if they have the rotavirus vaccine. Live virus can be shed in the baby's poo for up to 14 days. Make sure you wash your hands and/or wear gloves when changing their nappy.



There is some evidence that your baby may be more prone to infections if you take azathioprine or mercaptopurine along with other anti-TNF medicines, like infliximab.

Discuss the risks and benefits of taking infliximab while you are pregnant with your IBD team. You can also find out more in our information on <u>pregnancy</u> and <u>reproductive</u> <u>health</u>.

Breastfeeding

You can take infliximab while breastfeeding. Speak to your IBD team if this is something you are thinking of doing.

Experts agree that breastfeeding while on infliximab is unlikely to be harmful to your baby. Studies of babies that were breastfed by people taking infliximab have shown:

- Normal growth
- Normal development
- Normal rates of infection

Some studies have found small amounts of infliximab in breast milk. Infliximab can not be taken by mouth because it is broken down and destroyed in the gut. Infliximab in breast milk is also likely to be broken down in your baby's gut, so very little is likely to be absorbed by your baby. Speak to your IBD team if you are worried.

Your breastfed baby and live vaccines

Tell your baby's healthcare team if you are taking infliximab while breastfeeding. Manufacturers of infliximab recommend that breastfed babies should not be given live vaccines. But there might be times when it is OK for your baby to have a live vaccine. For example, if tests show that infliximab has not been found in their blood. Sometimes the benefit of giving a live vaccine while breastfeeding might be greater than the potential risk. You might want to discuss this with your IBD team and your baby's healthcare team. This includes the rotavirus vaccine and the BCG vaccine for tuberculosis. The BCG vaccine is not routinely given as part of the NHS vaccination schedule but is sometimes



recommended. Taking infliximab during pregnancy should not affect the rest of your baby's <u>vaccination schedule.</u>

Drinking alcohol

There is no need to avoid drinking alcohol while on infliximab. But you should follow <u>NHS</u> **guidelines** on counting your weekly alcohol units to reduce general health risks.

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 <u>Helpline</u> 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. You can also check the Patient Information Leaflet that comes with your medicine or visit medicines.org.uk/emc/.

About this information

We follow **strict processes** to make sure our information is based on up-to-date evidence and easy to understand.

Please email us at evidence@crohnsandcolitis.org.uk if:

CROHN'S&COLITISUK

· You have any comments or suggestions for improvements

You would like more information about the sources of evidence we use

You would like details of any conflicts of interest

You can also write to us at Crohn's & Colitis UK, 1 Bishop Square, Hatfield, AL10 9NE, or contact us through our Helpline: 0300 222 5700

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.

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 <u>crohnsandcolitis.org.uk</u>.

About our information

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.

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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