# CROHN'S & COLITIS UK Infliximab

If you've been prescribed infliximab, or are considering it as an option, you're not alone. Infliximab is a common treatment for people with <u>Crohn's Disease</u> and <u>Ulcerative Colitis</u>.

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

Starting infliximab may change your risk level for coronavirus. Check your risk here.

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# Key facts about infliximab

- 1. Infliximab is used to treat Crohn's and Colitis, but it doesn't work for everyone.
- 2. You'll first take infliximab through a drip into a vein in your arm (intravenous infusion). You may then continue to take infliximab by infusion or change to an injection under your skin (subcutaneous injection).
- 3. Infliximab affects the way your immune system works. This means you may be more at risk of infections. You may be advised to take extra precautions.
- 4. Tell your IBD Team if you notice any side effects, or if you have signs of an infection.
- 5. You should not have any live vaccines while taking infliximab. You can have the yearly flu jab, as this is not live.

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# Other names for this medicine

Infliximab for infusion is known by the brand names Flixabi, Inflectra, Remicade, Remsima and Zessly. Infliximab for subcutaneous injection is known by the brand name Remsima. It will be prescribed by brand name. You may need to ask your healthcare professional what brand you take if you have an infusion of infliximab.

Remicade was the first brand of infliximab. Flixabi, Inflectra, Remsima and Zessly are 'biosimilars' of Remicade but work in the same way. They are very similar to Remicade with the same treatment effects. But there are some slight differences, such as different ingredients to prolong shelf-life. 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, age 45 Living with Ulcerative Colitis

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# What infliximab is and how it works

Infliximab is a man-made antibody. The antibody is made from living cells, so it's known as a biological medicine.

Infliximab targets a protein in the body called tumour necrosis factor-alpha (TNF-alpha). TNF-alpha is naturally produced by your body. It plays an important role in helping your immune system fight infections. But too much TNF-alpha can damage the cells lining the gut. This is thought to partly cause the gut inflammation of people with Crohn's or Colitis. Infliximab binds to TNF-alpha, blocking its harmful effects and reducing inflammation. This helps to relieve symptoms.

You may also hear infliximab called an 'anti-TNF' medicine. Other anti-TNF medicines are:

- adalimumab (used to treat Crohn's and Colitis)
- golimumab (used to treat Colitis)

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## 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 Disease (including Crohn's Colitis)
- moderately to severely active Ulcerative Colitis

It may be given to you if other treatments (such as <u>steroids</u> or immunosuppressants, like <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

You are being offered infliximab to try to get your Crohn's or Colitis into remission. Keeping your Crohn's or Colitis under control is good for your long-term health. It reduces your risk of complications and needing surgery.

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>

**Remission** is when you feel better because your Crohn's or Colitis is being controlled well. Medical tests (like blood tests and endoscopy) show your gut is being affected less by your condition. Your symptoms, such as diarrhoea, abdominal pain, fatigue (extreme tiredness) or weight loss will improve. However, some symptoms, like fatigue, may not go away completely.

#### Acute Severe Ulcerative Colitis (ASUC)

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

#### Other health conditions

Infliximab is also to treat rheumatoid arthritis, ankylosing spondylitis, psoriasis, and psoriatic arthritis.

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## Deciding which medicine to take

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

There are many things to consider when choosing a treatment. As well as overall effectiveness, you may want to ask your IBD team which medicine is likely to start working fastest. You may also want to think about whether injections or infusions fit better with your lifestyle. Our <u>Appointments Guide</u> has some questions to get you started. It can help you focus on what matters most to you.

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# How effective infliximab is in Crohn's and Colitis

Infliximab can be effective at getting and keeping your Crohn's or Colitis under control (in remission).

#### Talking about the effectiveness of medicines

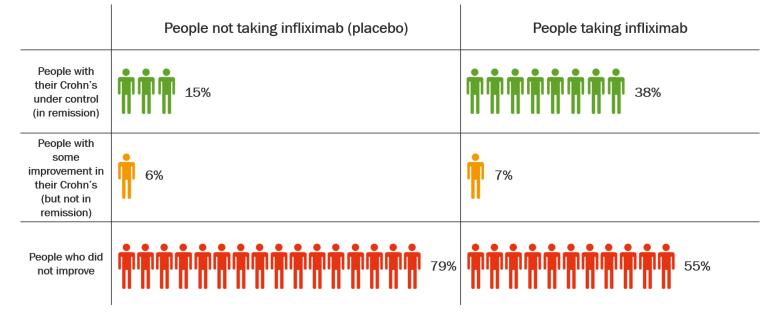
To see how effective a medicine is, we can look at data from clinical trials. Clinical trials are used to test a medicine. However, this data may not completely represent what happens when medicines are given to you by your IBD team. In clinical trials, people are often removed from the trial if they do not respond quickly to a medicine. This won't happen when you start taking infliximab. Your IBD team may advise you take it for a longer time to see if you respond. They'll also make sure the dose is right for you before suggesting you stop taking it. This means infliximab may be more effective than the data from clinical trials shows.

The best clinical trials include people who were not taking the medicine. This is known as a placebo or control group. This is important. It allows us to see how many people have got better because of the medicine, as well as people who may have got better anyway (without the medicine).

#### 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 Disease.

More than twice as many people had their Crohn's under control (in remission) after taking infliximab for one year compared with people who had not been taking infliximab (placebo). But, not everyone responds to infliximab.



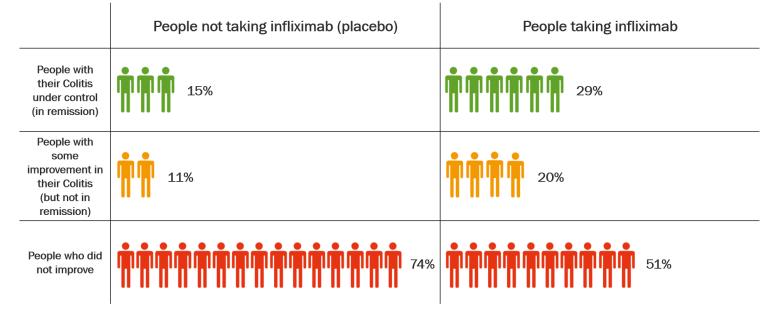
After one year of treatment...

#### If you have Ulcerative Colitis

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

Twice as many people had their Colitis under control (in remission) after taking infliximab for one year compared with people who had not been taking infliximab (placebo). But, not everyone responds to infliximab.

After one year of treatment...



"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, 32 Living with Crohn's Disease

# How long infliximab takes to work

Everyone responds differently when taking a new medicine. You may feel better soon after starting treatment – but you'll probably need 2 or 3 doses before you feel better.

Infliximab doesn't work for everyone. It's important that you are checked by your IBD team to see how well it is working for you.

## How to take infliximab

Infliximab cannot be taken by mouth as a tablet because it would be destroyed by your digestive system. It can only be prescribed by a specialist in the hospital. It is not a medicine that your GP can prescribe for you to pick up from your local pharmacy. You won't have to pay for your infliximab prescription, as long as you're entitled to NHS care.

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Infliximab is usually given through a drip into a vein in your arm (intravenous infusion). Some hospitals may offer the option to take infliximab by injection (adults only). This is using a pre-filled pen or syringe that you inject yourself under your skin (subcutaneous injection). Even if you take infliximab by injection, you'll first need to have two doses of infliximab by infusion in hospital. Infusions and injections are both as effective in treating Crohn's and Colitis. Ask your IBD team how you will be taking infliximab.

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#### 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. 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 overnight.

Your first infusion usually takes about two hours, plus one to two hours after so your healthcare team can check how you are. You may need to set aside at least half a day for your first infusion. 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 had a few infusions.

Your medical team will monitor you during and after your infusion to check that you do not develop an allergic reaction. If you've previously had a reaction, your infusion may take longer to reduce your risk of another reaction. You may be given paracetamol, antihistamine or hydrocortisone just before the infusion. This can minimise 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. Others prefer to go home as the infusion can make you feel sleepy.

"When I was doing my PhD, whilst getting my infusions, I worked on chapters, and did some reading, editing and proofreading 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, age 40 Living with Crohn's Disease

# **Dosage information for infusions**

If you're taking infliximab by infusion only, 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 make up the infusion for you.

For both Crohn's and Colitis, you'll have an initial infusion followed by another infusion two weeks later. You'll have a third infusion four weeks after that. If you respond well, you'll be put onto maintenance dosing of an infusion every eight weeks.

If infliximab doesn't work for you, or it becomes less effective, your doctor may suggest that you try a higher dose or more frequent infusions. This will be based 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 be.

Dosing schedule in adults and children		Continue ever	Continue every 8 weeks	
Week 0	Week 2	Week 6	Week	Week
			14	22
5mg/kg	5mg/kg	5mg/kg	5mg/kg	5mg/kg
Infusion	Infusion	Infusion	Infusion	Infusion
in	in	in	in	in
hospital	hospital	hospital	hospital	hospital
Induction doses		Maintenar	nce doses	

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## How to 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.

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 you the injections.

Infliximab comes ready to use in either a pre-filled syringe or a pre-filled injection 'pen'. You may not see the needle in the injection pen, as it's inside. The syringes or pens come in a pack. The pack contains an alcohol pad to clean your skin before injecting.

#### Delivery

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

#### Storage

Infliximab should be kept in the fridge. But, if you are travelling, it can be stored at room temperature (up to 25°C) out of sunlight for up to 28 days. If it's not used within this time you will need to get rid of it. Do not put it back in the fridge. Unused medicines should be disposed of safely by your pharmacist. Find out more about travelling with medicines in our information on <u>Travel</u>.

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# 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. You should expect to feel some pain, but these tips can help to make it easier to manage:

• Let your medicine warm to room temperature

Injecting yourself with cold medicine from the fridge may be uncomfortable. Take it out of the fridge 15-30 minutes before you inject, so it can warm to room temperature. Do not warm the injection in any other way, such as in hot water or a microwave.

# • Choose your injection site

The upper thigh or stomach (away from the belly button) are good places for the injection. Avoid any areas where the skin is red, scarred, bruised or hard. Use an area at least 3cm away from any previous sites so a hard lump doesn't form.

- Use an ice pack before you inject
  Apply an ice pack to the area for 2-3 minutes before you inject. Place a thin towel between the ice pack and your skin.
- Wash your hands and clean the skin at the injection site Wash your hands with soap and water. Clean your skin with an alcohol wipe before

you inject to reduce the risk of infection.

# Use a good injection technique if you use a syringe

Use a quick, dart-like 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. If you use a syringe the injection will take about 2-5 seconds. If you use a pen this will take about 10 seconds.

#### • Use an ice pack after you inject

An ice pack or cold damp towel may help with pain at the injection site. Do this for about 10-15 minutes. Remember to place a thin towel between the ice pack and your skin.

#### • 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.

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# **Dosage information for injections**

Your first dose will be given by infusion in hospital, with 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**.

You will then change to dosing by injection if you respond well. 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. This will be done based 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 be. You must not make any dose changes unless your IBD team have told you to.

Dosing schedule (adults only)		C	Continue every 2 weeks		
Week 0	Week 2	Week 6	Week 8	Week 10	
5mg/kg	5mg/kg	120mg	120mg	120mg	
Infusion in hospital	Infusion in hospital	Injection in hospital <b>or</b> nurse at home	Self- inject at home	Self- inject at home	
Inc	luction doses		Maintenance doses		

# How long you'll take this medicine

You are likely to have a planned course of treatment for up to a year if infliximab is working well for you. After that, your treatment plan may be extended. You will be checked at least every 12 months to make sure infliximab is still right for you.

# Stopping or changing treatment

There are a few reasons why you and your IBD team may think it's right to stop or change your treatment:

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Infliximab is not effective – if this medicine hasn't worked for you within 6-16 weeks. 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 and try changing your dose before suggesting you stop treatment.

- Stable remission if your condition is in stable remission after 12 months of treatment. If you relapse (have a flare-up) after treatment has stopped, you should be able to start infliximab again. Re-starting anti-TNF treatment will be successful in nearly 9 in 10 people (88%) with Crohn's and 3 in 4 people (76%) with Colitis.
- Side effects if you have side effects that are serious or hard to manage.
- Infliximab becomes less effective some people develop antibodies to infliximab over time, which can stop it working. Your antibody levels will be checked using a blood test.

You have a right to take part in decisions about your treatment. Tell your IBD team what matters most to you, so they can give you the information and support you need. Our <u>Guide to Appointments</u> can help you have these conversations. Do not stop taking your medicine unless your IBD team have said it's ok. If you have to stop taking this medicine but you're still unwell, you may be able to try a different biologic. See our information on <u>biologic medicines.</u>

# Taking infliximab with other Crohn's or Colitis treatments

You may take infliximab with other medicines for your Crohn's or Colitis, such as <u>5-ASAs</u> (like mesalazine), thiopurines (<u>azathioprine or mercaptopurine</u>) or <u>methotrexate</u>. 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 azathioprine or methotrexate may be more effective. This can reduce the risk of infliximab becoming less effective over time. Speak to your IBD team about the risk of extra side effects with combination therapy. You should decide together what the best treatment option is for you.

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#### Checks before starting this medicine

Checks before treatment – such as blood tests and imaging – are important to make sure that infliximab is right for you.

14 Crohn's & Colitis UK To help your IBD team, tell them if you have a history of:

- **Tuberculosis (TB).** If you've had TB or you've recently been with someone who has TB. 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, or if you are generally feeling unwell or feverish. You may need to delay your treatment if you have an infection.
- HIV, hepatitis B or C. This includes any past or current infections, if you are a carrier of hepatitis B or C (a liver infection caused by a virus), or have been in close contact with someone who has hepatitis B or C. You will have a blood test to check for these diseases.
- Heart problems. Your heart will need to be monitored closely before, during, and after treatment as it could make your heart problems worse.
- **Cancer.** Infliximab affects how your immune system works and may increase the risk of some types of cancer. You may also be at risk even if you do not have a history of cancer.
- **Pre-existing conditions,** including allergies, COPD (Chronic Obstructive Pulmonary Disease), asthma, kidney disease, liver disease, multiple sclerosis or 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 are taking any other medicines
- you have had any vaccinations recently or plan to have any
- you have had surgery, or plan to have surgery or dental treatments
- you travel to regions of the world where TB or fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis are common

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- you have ever had chicken pox, shingles or measles. You may be able to be vaccinated against these before you start treatment.
- you have a fistula or an abscess. Infliximab can help to close fistulas but abscesses must be drained first.

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## **Ongoing checks**

You'll need regular checks while taking infliximab, including blood tests. This helps your IBD team fit your treatment to your needs. It can help make sure that any problems with treatment are avoided or caught 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 in your blood and to see if you've developed antibodies. This helps your IBD team to see if the treatment is working or if your dose needs changing.

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

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## **Special precautions**

You may feel drowsy after your infusions, especially if you've had medicine to reduce side effects. It could be a good idea to arrange a taxi or someone to drive you home after.

If you feel dizzy or tired after taking this medicine do not drive or use any tools or machines.

This medicine affects the way your immune system works. Your immune system is still able to fight off infections, just not quite as well as other people. You may find that infections affect you more than they used to, or it takes you longer to recover. Tell your IBD team if you develop signs of an infection, such as a sore throat, fever or any new symptoms that concern you. They may advise you to wait until you feel better before injecting. Less often, more serious infections can be a side effect of infliximab. See the section below on **Side effects**. Even though your risk of complications may be higher when taking infliximab, it shouldn't stop you from living life as before. There are a few extra precautions your IBD team may advise you to take to keep safe and reduce your risk:

- Have the annual flu vaccination. You may also be advised to have a pneumococcal vaccine. Ask your IBD team if you'll need to have this just once, or every 5 years.
- Avoid close contact with people who have serious infections. This includes chickenpox and shingles, measles, TB and 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. You're still able to go out and socialise as before, but it's sensible to be more careful. Wash your hands regularly with soap and water (or use an alcohol-based hand gel) – especially 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, such as Listeria or Salmonella. Avoid eating raw eggs or undercooked pate, meat and poultry, as well as unpasteurised milk or cheeses. Nearly all dairy sold in UK supermarkets is pasteurised and safe to eat This includes soft and 'blue' cheeses – just check the label if you're 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. Azathioprine and mercaptopurine, which you may also be taking as combination therapy, can also increase this risk. Practice good sun safety such as wearing a hat and high factor sunscreen, staying in the shade when you can and avoiding sunbeds. The <u>NHS website</u> has more tips for staying safe in the sun.
- Women and people with a cervix should attend routine screening for cervical cancer (previously known as the smear test). Abnormal cell changes in the cervix are caused by the human papilloma virus (HPV). Immunosuppressed women are more likely to have these abnormal cell changes. However, there is no evidence linking cervical cancer to the use of infliximab or other biologics. There's no need to be tested more often than other women. You'll be invited to routine screening

by your GP.

"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, age 65 Living with Crohn's Disease

# Side effects

All medicines can have unwanted effects, although not everyone will get them. Some side effects can happen right away, others may develop later. Some can even last for short time after you stop treatment.

Some side effects may be mild and go away on their own, or when the medicine is stopped. Others may be more serious and will need managing or may mean that the treatment is not right for you. Try to consider how unwell any side effects are making you feel, as well as the benefits of taking this medicine to keep your Crohn's or Colitis under control.

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

#### Tell your doctor or IBD team immediately if you develop:

- Symptoms that may mean you are having a reaction to the infusion/injection or an allergic reaction:
  - Hives (red, raised, itchy patches of skin) or other skin rashes
  - o Trouble breathing or swallowing, or shortness of breath
  - o Pains in your chest or muscles or joints
  - o Fever or chills
  - Swelling of your face, hands or feet
  - Headaches or a sore throat

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- Symptoms of an infection or if you come into contact with someone with a serious infection. Look out for:
  - Feeling feverish, generally unwell or flu-like symptoms
  - Feeling overly tired
  - A cough with mucus/sputum
  - o Warm painful skin
  - Stinging when passing urine
  - An open cut or wound
  - Tooth or gum pain or swelling
- Other symptoms to look out for:
  - Bruising, bleeding or paleness
  - Changes in your vision
  - Numbness or tingling
  - o Joint swelling

#### Most common side effects

Around 1 in every 10 people taking infliximab may have:

- Infusion or injection site related reactions (redness, swelling or pain where you've injected)
- Upper respiratory tract infections (like colds, tonsilitis and sinus infections) or flu
- Tummy pain or feeling sick (nausea)
- Headaches

#### Other side effects

- Infections. You may need to delay your infliximab dose if you have an infection. Ask your IBD team for advice.
  - Common: Urinary tract infections, conjunctivitis. More serious infections include cellulitis (a bacterial skin infection) or sepsis (when your immune system overreacts to an infection, damaging your body).
  - Uncommon: You may be at greater risk of developing TB, or reactivating underlying TB.

- **Gut problems.** Some of these will be similar to the symptoms of Crohn's or Colitis. Speak to your IBD team if you're not sure what may be causing your symptoms.
  - Common: Diarrhoea, 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 (feeling like you or everything around you is spinning).
  - Rare: Demyelination disorders (damage to nerves).
- **Blood problems.** Symptoms include a fever that does not go away, bruising or bleeding very easily, sore throat, or looking pale.
  - Common: 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: Tachycardia (increased heart rate) or palpitations (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 feel very tired with a lack of appetite, or you have a persistent pain on the right-hand side of your tummy (abdomen).
  - 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 and will use blood tests to check it does not activate.
- Skin reactions. Some of these can be treated without stopping infliximab.
  - Common: Psoriasis (scaly patches), eczema, other skin rashes, dry skin.
  - $\circ$   $\,$  Uncommon: Ulcers or warts.
- Some types of skin cancer. You must tell your doctor if you have a bump or open sore which is not healing.

- Rare: Melanoma.
- Other types of cancer. This medicine may not be right for you if you've previously had cancer.
  - Rare: Lymphoma or leukaemia (types of blood cancer).
  - Not known: A rare and serious cancer called hepatosplenic T-cell lymphoma (HSTCL). HSTCL has been found in some people taking anti-TNF medicines in combination with azathioprine or 6-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.
	taking initiatinab may develop this side enect.
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 <u>medicines.org.uk/emc/</u>.

We'd 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. Report your side effect at <u>yellowcard.mhra.gov.uk</u>

"I was terrified about starting infliximab but I was pleased that

I was monitored so closely with pre screening checks, regular

blood tests and access to the IBD helpline."

Angela, age 36 Living with Crohn's Disease

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# Taking other medicines

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

However, infliximab may interact with other medicines. Speak to your doctor or pharmacist if you're taking, or plan to take any other medicines. This includes over the counter medicines (medicines that you buy yourself) and 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

Tell any doctor, dentist or health professional treating you that you are taking infliximab. Always carry the alert card that comes with the medicine while you are taking it and for up to six months after your last dose.

# Vaccinations

It's not safe to have 'live' vaccines while taking infliximab. It can take up to six months after your last dose for infliximab to completely leave your body. However, it's safe to have live vaccines 3 months after your last dose of infliximab. Ask your IBD team to make sure your vaccinations are up to date before you start infliximab, or if you're planning to travel. If you've recently had a live vaccine you may have to wait 4 weeks before starting infliximab.

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)
- Flu nasal spray (children only)

Everyone with Crohn's or Colitis taking a biologic medicine should have the yearly flu jab. This is not a live vaccine and is safe to have while taking infliximab.

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

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# **Pregnancy and fertility**

Infliximab does not affect fertility. If you don't want to get pregnant you should use contraception.

Talk to your IBD team if you're taking infliximab and planning a pregnancy or are already pregnant. If you decide to continue taking infliximab, it should not stop you having a normal pregnancy and a healthy baby. Research shows that anti-TNF medicines, like infliximab, do not affect your pregnancy, or harm your baby. Long-term health, infection rates and development do not appear to be affected in children of mothers taking anti-TNFs during pregnancy. This includes mothers who took anti-TNFs until birth).

Infliximab does not appear to affect foetuses, but there hasn't been enough research to rule out the possibility completely. To be cautious, drug companies state that infliximab should only be used during pregnancy if needed to keep your condition under control. This is because the medicine could cross the placenta. They recommend using contraception to prevent pregnancy while taking infliximab and for at least six months after your last dose. However, infliximab is generally considered safe. Your IBD team may advise the safest option is to keep taking it during pregnancy to keep your Crohn's or Colitis under control.

When deciding whether to continue taking infliximab, you should consider the risks of having a flare-up while you're pregnant. Having active Crohn's or Colitis can lead to premature (early) birth, low birth weight and higher rates of miscarriage. It's important to keep your condition under control in pregnancy. If your Crohn's or Colitis is well controlled (remission), then your IBD team may recommend that you take infliximab for the first six months of your pregnancy (first and second trimesters), but stop during third trimester. 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 entire pregnancy to keep you well.

You must tell your baby's healthcare team you were taking infliximab while pregnant. It is advised that if you take infliximab during your pregnancy your baby should avoid live vaccines until they are at least six months old. This includes the BCG for tuberculosis and the rotavirus vaccine. It should not affect the rest of your baby's <u>vaccination</u> <u>schedule.</u>

Take extra care if your baby does have the rotavirus vaccine, as 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 6-mercaptopurine along with anti-TNFs, like infliximab.

Discuss the risks and benefits of taking infliximab while pregnant with your IBD team. You can also find out more in our information on <u>Pregnancy</u> and <u>Reproductive Health</u>.

There is less research on men wanting to father a child while taking anti-TNF medicines. But it's generally considered safe for a man to conceive a child.

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## Breastfeeding

You can take infliximab while breastfeeding. Some studies have found very small amounts of infliximab in breast milk. Other studies have not been able to detect infliximab in breast milk. Infliximab has been found in some breastfeeding babies – but some mothers were also taking infliximab during pregnancy. It's possible infliximab could have transferred to the baby during this time.

Drug companies recommend that you stop taking infliximab at least six months before you start breastfeeding. However, there is very little risk to your baby. Your IBD team may suggest you keep taking infliximab while breastfeeding if it's keeping your Crohn's or Colitis under control.

Small studies of babies breastfed by mothers taking infliximab have shown normal growth, development and rates of infection. Speak to your IBD team if you're worried.

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# **Drinking alcohol**

Alcohol is not known to have any interaction with infliximab.

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# Who to talk to if you're 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 <u>medicines.org.uk/emc</u>.

# 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

25 Crohn's & Colitis UK 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 <u>crohnsandcolitis.org.uk/membership</u> for more information, or call the Membership Team on 01727 734465.

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© Crohn's & Colitis UK 2020 Infliximab Edition 8b Amended 2021 Last review – Nov 2020 Next full review – 2023 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 Evidence 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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# 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.