



Adalimumab

Adalimumab is a common treatment for people with <u>Crohn's</u> and <u>Colitis</u>. This information is for people who take this medicine or are thinking about taking it.

Our information can help you 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 healthcare 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 the <u>Electronic Medicines Compendium</u>.

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Key facts about adalimumab

- Adalimumab is used to treat Crohn's and Colitis. It can be given to adults or children who are six years old or over. Adalimumab does not work for everyone.
- You take adalimumab by injection under your skin. You will usually take this every two weeks. You may be able to use a pre-filled syringe or a pre-filled injection pen.
- Adalimumab 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 live vaccines while taking adalimumab. But having annual flu
 and COVID-19 vaccinations can help protect you. These are safe to take because
 they are not live vaccines. You may also be invited to have a non-live pneumococcal
 vaccine. If you're over 50, you may be offered a non-live version of the shingles
 vaccine.
- Adalimumab is generally considered safe to take during pregnancy. Talk to your IBD team if you are thinking of having a baby.

Other names for this medicine

Adalimumab is known by several brand names, including:

- Amgevita
- Humira
- Hyrimoz
- Idacio
- Imraldi



Yuflyma

Your medicine will be prescribed by brand name.

Humira was the first brand of adalimumab. Amgevita, Hyrimoz, Idacio, Imraldi and Yuflyma work in the same way but are known as 'biosimilars'. This means they are similar to Humira and have the same treatment effects. There may be some slight differences between brands, such as:

- How the injection device works. Some devices have a needle that goes back into the injection device. This is known as an injection pen.
- · How much adalimumab they contain and how concentrated they are
- Needle size
- The other ingredients they contain. Some brands may include ingredients that prolong shelf-life. Some brands may take out certain ingredients so that injections are less painful
- How long you can store them outside of the fridge
- Licensed indication. A licensed indication is how a medicine or brand of medicine can be used according to the law. For example:
 - Some Hyrimoz products are not licensed for Ulcerative Colitis in children.
 This includes:
 - Hyrimoz 40mg pre-filled pen (low concentration)
 - Hyrimoz 40mg pre-filled syringe (low concentration)
 - 'Humira 20mg pre-filled syringe' is for use in children only
 - o 'Idacio 40mg/0.8ml injection for paediatric use' is for children only

The brand you are given will not affect your treatment, but you may want to ask your healthcare professional which brand you take. For more about biosimilars see our information on <u>biologic medicines</u>.

"Adalimumab is my little bit of magic in a pen: I have been on this treatment over 3 years."

Thea

Living with Crohn's

What is adalimumab and how does it work?

Adalimumab belongs to a group of medicines called <u>biologic medicines</u>. These medicines are made by a biological rather than a chemical process. They are made in a lab from living cells.



Adalimumab is a man-made antibody-based medicine. An antibody is a protein that is part of your natural defences. Adalimumab targets a protein in the body called tumour necrosis factor-alpha, known as 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. Adalimumab binds to TNF-alpha, blocking its harmful effects. This can reduce inflammation and help to relieve symptoms.

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

- Golimumab. This is used to treat Colitis
- Infliximab. This is used to treat Crohn's and Colitis

Why you might be offered adalimumab

Adalimumab is used to treat adults and children from 6 years old with:

- Moderate to severely active Crohn's Disease
- Moderate to severely active Ulcerative Colitis

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

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

Adalimumab may also:

- Be effective when infliximab, another type of anti-TNF, has not worked
- Reduce the risk of a Crohn's flare-up after surgery
- Treat fistulas in people with Crohn's. Find out more in our information on Fistulas

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 well-controlled. During this time, medical tests, such as blood tests or 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 the need for surgery.



Other health conditions

Adalimumab is also used to treat:

- Certain types of arthritis
- Some skin conditions
- · Uveitis. This is inflammation on the inner part of your eye

Deciding which medicine to take

You may be given a choice of taking adalimumab or another biologic medicine. Our information on medicines for Crohn's and Colitis can help you decide.

There's lots 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 what you'd like to get out of 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
- Other conditions you have
- If you are planning to get pregnant or breastfeed in the next few years
- What happens if you do not take it

You could use our <u>medicine tool</u> to help you think about your options. Our <u>appointment</u> <u>guide</u> also has a list of questions you might want to ask your IBD team. We also have information on <u>other medicines</u> or <u>surgery for Crohn's or Colitis</u>.

How well does adalimumab work in Crohn's and Colitis?

Adalimumab 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**.

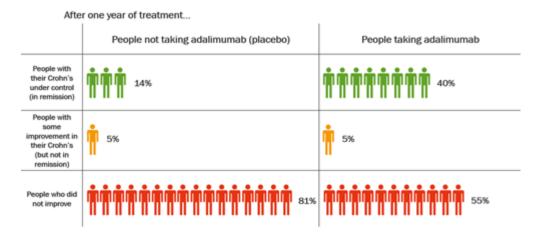
The information below shows the results of clinical trials that looked at how effective adalimumab is. To find this out, scientists compared people who took adalimumab with people who took a placebo. A placebo is a substance that looks the same as the treatment but does not have any medicine in it.



If you have Crohn's Disease

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

After one year of treatment with adalimumab, an average of 4 in every 10 people, or 40%, were in remission. Of those who took a placebo, an average of less than 2 in every 10 people, or 14%, were in remission. These statistics show that more than twice as many people had their Crohn's under control after taking adalimumab for one year, compared with people who had not been taking adalimumab. But adalimumab does not work well for everyone with Crohn's.



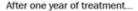
If you have Ulcerative Colitis

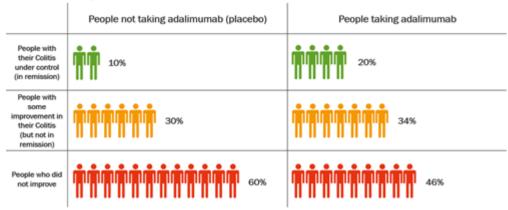
The table below shows data from clinical trials of adalimumab in adults with moderate to severely active Colitis.

After one year of treatment with adalimumab, an average of 2 in every 10 people, or 20%, were in remission. Of those who took a placebo, an average of 1 in every 10 people, or 10%, were in remission. This shows that twice as many people had their Colitis under control after taking adalimumab for one year, compared with people who had not been taking adalimumab. But adalimumab does not work well for everyone with Colitis.









How quickly adalimumab works

Everyone responds differently when taking a new medicine. You may feel better soon after starting treatment. It may take up to 12 weeks if you have Crohn's, or up to eight weeks if you have Colitis.

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

How to take adalimumab

Adalimumab is given as an injection under the skin. Adalimumab cannot be taken as a tablet. This is because if you swallowed adalimumab, it would be broken down by your gut before it could start working.

Your IBD team will monitor your treatment. Your first dose will usually be given to you in hospital, or by a trained nurse at home. You will 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.

Adults

Adalimumab for adults 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 and pens both come in a pack. Each pack contains an alcohol pad to clean your skin before you inject.

Children

Adalimumab for children comes ready to use in either a pre-filled syringe, a pre-filled injection 'pen' or in a small bottle, known as a vial. For the injection pen, the needle is inside the device and may not be seen. The vial is designed to fit onto a syringe using an



adapter. Only the brand Idacio comes in a vial. The syringes or pens come in a pack. Each pack contains an alcohol pad to clean your skin before you inject.

Delivery

Adalimumab will usually be sent to your home by a special delivery company. You cannot pick it up from your local pharmacy.

Storage

Keep adalimumab in the fridge.

If you are travelling, you can keep your adalimumab out of the fridge. If you do keep it out of the fridge it must be kept out of the sunlight and stored at room temperature, or below 25 °C. Your medicine can be kept this way for up to:

- 14 days for Amgevita and Humira
- 21 days for Hyrimoz
- 28 days for Idacio and Imraldi 0.8ml injection pen and syringe. For Imraldi, this
 concentration is only available in England. People living in Scotland, Wales or
 Northern Ireland may have this medicine if it was dispensed before September 1,
 2024
- 30 days for Yuflyma
- 31 days for Imraldi 0.4ml injection pen and syringe. This concentration is only dispensed in Scotland, Wales or Northern Ireland after September 1, 2024

Ask your pharmacist to get rid of your adalimumab if it is not used within this time.

Do not put your medicine back in the fridge once it has been kept at room temperature.

Always check the leaflet that comes with your medicine.

Find out more about travelling with medicines.

Tips on injecting

Make sure you know how your injection device works.

Different brands use different methods. For some, you will need to pinch your skin before you inject. For others, you may need to press a button to inject the medicine. Check the leaflet that comes with your medicine.

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



• Let your medicine warm to room temperature

Injecting yourself with adalimumab straight from the fridge may feel uncomfortable. Try taking it out of the fridge 15 to 30 minutes before you inject. 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 tummy. If you inject it into your tummy, choose somewhere at least 5cm away from your belly button. Avoid any areas where the skin is sore, bruised, red, is scarred or has stretch marks. 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

Put an ice pack on the area for two to three minutes before you inject. This can help to numb the area. 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

There are several things you can do to reduce the risk of infection:

- Wash your hands with soap and water
- Clean your skin with an alcohol wipe before you inject yourself

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. When you are finished, release your thumb and gently remove the syringe from your skin at the same angle as it was inserted.

For the pre-filled pen, instructions on how to inject yourself may vary. Always check the leaflet that comes with your medicine or ask your IBD team how to use an injection pen.

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 or read the leaflet that came with your medicine.





"The thought of injecting myself filled me with dread, but it was so easy and is now just a part of my life that I don't even think about!"

Karen Living with Crohn's

Dosage information

Your first injection will be a higher dose. You may need more than one injection for this. This is because the amount of solution needed to make up the higher dose is too much to inject in one go.

The first few doses are known as induction doses. These can help you respond to the medicine quickly. After your first dose, you will have another induction dose two weeks later. If you respond well, you will usually have maintenance dosing every two weeks.

Some people may need a quicker response to their medicine. To help with this, their induction dose may be increased. Increasing the dose may increase the risk of side effects.

If adalimumab does not 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 and blood test results. Speak to your IBD team if you think your medicine is not working as well as it should. Do not make any dose changes unless your IBD team tells you to.

Talk to your IBD team or look at the leaflet that comes with your medicine to see how much you should take.

How long will I be on adalimumab?

If adalimumab works well, you will continue your treatment for a few months. After this, your IBD team may check if this medicine is still helping you. If you are responding well and it is not causing you any serious side effects, then you will continue treatment. Your IBD team should assess you at least every eight to twelve months to check adalimumab is still right for you. Adalimumab is safe to take for a long time and many people use it for many years.

Stopping or changing treatment



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

- Adalimumab is not effective. Your IBD team will give your medicine two to three
 months to work. They may stop treatment if it has not 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 how
 often you have your dose or the strength of your dose before suggesting you stop
 treatment.
- Your Crohn's or Colitis is under control. You may be able to stop your medicine if your condition is under control for a while. If you become unwell again, you should be able to restart adalimumab. Re-starting anti-TNF treatments, like adalimumab, is successful in nearly 9 in 10 people, or 88%, with Crohn's and nearly 8 in 10 people, or 76%, with Colitis.
- Side effects. You may need to stop taking adalimumab if you have side effects and they:
 - o Are serious
 - o Affect your daily life
 - Are hard to manage
- Adalimumab becomes less effective. Over time, some people develop antibodies
 to adalimumab. An antibody is a protein that is part of your natural defences. This
 can stop your medicine from working. Your antibody levels will occasionally be
 checked using a blood test.
- **Issues with injecting yourself.** You may prefer to try a treatment that you can have by an intravenous infusion in hospital.

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 <u>guide to appointments</u> can help you have these conversations. Do not stop taking your medicine unless your IBD team says 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 <u>biologic medicines</u>.

Taking adalimumab with other Crohn's or Colitis treatments

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

- 5-ASAs, such as mesalazine
- Thiopurines, such as <u>azathioprine or mercaptopurine</u>
- <u>Methotrexate</u>. This is particularly used for treating Crohn's disease and less commonly for ulcerative colitis.



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 adalimumab with methotrexate or a thiopurine, such as azathioprine, may be more effective. This can reduce the risk of adalimumab 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 adalimumab is right for you. This will involve asking about any pre-existing conditions and having some tests. This may include blood tests and imaging, such as an X-ray.

Pre-existing conditions

- Tell your IBD team if you have:
 - Allergies
 - COPD, known as Chronic Obstructive Pulmonary Disease
 - o Asthma
 - Kidney disease
 - Liver disease
 - Multiple sclerosis
 - Heart problems. If you have heart problems, adalimumab may not be right for you. If your doctor thinks it is safe, they may check on your heart before, during and after treatment. In rare cases, adalimumab could make your heart problems worse.
 - Cancer. This medicine can increase your risk of certain types of cancer.
 Adalimumab may not be right for you if you have previously had cancer
 - Any other disease or symptoms affecting the nervous system

Infection risk

Having treatment that affects your immune system can mean that your body may not be able to fight off infections as well as it used to. Before you start adalimumab, your IBD team may ask you some questions and do some tests. This is to make sure your risk of an infection is as low as possible. Tell your IBD team if:



- You have an infection, or 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 ever had tuberculosis, also known as TB, or have recently been in close contact with someone who has TB. If you have TB, it will need to be treated before you start adalimumab. You will usually have a blood test and/or a chest X-ray to check for TB.
- You have HIV or hepatitis. Hepatitis is inflammation of the liver, which can be caused by certain viruses. You will usually have a blood test to check for these viruses.
- You have ever had chickenpox, shingles, cold sores or genital herpes. If necessary, 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 vaccinations are up to date. If they are not, your IBD team may suggest you
 have the ones you need. This is to help protect you from infections. Let them know
 if you plan on having any vaccinations, or if you had a vaccination recently. If you
 have had a live vaccine recently, you may need to wait a while before starting
 treatment.

Your life and lifestyle

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 in the future
- You have had surgery, or plan to have surgery or dental treatments
- You have traveled or are planning on traveling to regions of the world where you
 may have a higher risk of:
 - o TB
 - Fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis

Ongoing checks

You will be regularly monitored for any side effects and have checks to make sure that adalimumab is right for you. This may sometimes include blood tests. 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 adalimumab and antibodies in your blood. This helps your IBD team to see if adalimumab is working or if your dose needs changing.

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

Special precautions

Driving and using heavy machinery

Some people may feel dizzy or have blurred vision after taking adalimumab. Do not drive, ride a bike or use any tools or machines if you feel dizzy or tired after taking this medicine.

Infection risk

This medicine affects the way your <u>immune system works</u>. Your immune system can fight off infections, but it may not be as strong as before. You may find that you get more infections or that they affect you more than they used to. 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. Your IBD team may advise you to wait until you feel better before having adalimumab. Less often, serious infections can be a side effect of adalimumab. See the section below on **side effects**.

Although your risk of infections may be higher when taking adalimumab, it should not stop you from living life as before. See our information on <u>immunosuppressant</u> <u>precautions</u> to find out some practical things you can do to reduce your risk.

Take care in the sun

You may be more at risk of skin cancer. You should practice good sun safety, this includes:

- Wearing a hat
- Using high-factor sunscreen
- Staying in the shade
- Avoiding sunbeds

The NHS website has more tips for staying safe in the sun.

Attending 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 papillomavirus, known as HPV. If you are



immunosuppressed, you are more likely to catch HPV, which can cause these changes. Taking adalimumab does not automatically mean you need to be tested more regularly than other people. However, if you are HPV positive, you may need to go for screening more often. There is no evidence linking cervical cancer to the use of adalimumab or other biologics. 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.

Side effects

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

- Some side effects can happen right away. Others may happen after you have been taking adalimumab 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 adalimumab. Some may be long-lasting.

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

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 adalimumab might have an allergic reaction. Severe allergic reactions are rare. Life-threatening reactions are even more unusual.

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 adalimumab, you may get infections more easily. This is because adalimumab can affect your immune system. You might get more infections than you are used to. Infections may last longer or be more serious than usual. You may also be more likely to get an opportunistic infection. An opportunistic infection is an infection that happens more often or is more severe in someone with a weakened immune system.

Opportunistic infections can include infections like tuberculosis, shingles and thrush.

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
- A high temperature
- Feeling overly tired
- · A persistent cough with mucus or phlegm
- Shortness of breath
- · Diarrhoea or vomiting
- Stinging when passing urine
- Swelling or pain around a cut or a wound
- Tooth or gum pain or swelling

Other serious side effects

Symptoms of serious side effects do not happen often, but it is important to know what to look out for. Tell your doctor or IBD team immediately if you develop:

- A swollen face, hands, ankles or feet
- o Trouble breathing or swallowing
- o Shortness of breath when exercising or lying down



- A fever that does not go away
- Bruising, bleeding or paleness
- Weight loss
- Lack of energy or feeling more tired than usual
- Changes in your vision
- Weakness in your arms of legs
- Numbness or tingling in any part of your body
- A bump or open sore that will not heal
- Yellow skin or eyes
- Lack of appetite
- Pain on the right side of your tummy

Most common side effects

More than 1 in every 10 people taking adalimumab may have:

- Injection-site reactions. This might include itching, redness, swelling or pain where you have injected
- Flu, pneumonia, or upper respiratory tract infections, such as colds, runny nose or sinus infections
- Headache
- Tummy pain
- Being or feeling sick
- Skin rash
- Muscle or joint pain

Risk of cancer

This medicine may not be right for you if you have previously had cancer. You must tell your doctor if you have a bump or open sore that is not healing.

- Common. Between 1 in every 10 people and 1 in every 100 people who take adalimumab may be affected by skin cancer. This does not include melanoma, see the 'uncommon' list below.
- Uncommon. Between 1 in every 100 people and 1 in every 1,000 people who take adalimumab may be affected by:
 - Melanoma. This is a type of skin cancer
 - Lymphoma. This is a type of cancer of the lymphoid system. This helps protect your body from infections and diseases
- Rare. Between 1 in every 1,000 people and 1 in every 10,000 people who take adalimumab may be affected by Leukaemia. This is a type of blood cancer
- Not known: A rare and serious cancer called hepatosplenic T-cell lymphoma, also known as 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 has not been measured, but it is a rare cancer, and rarer still in people taking these medicines.

Finding out more

For a full list of side effects see the Patient Information Leaflet provided with your medicine or visit the <u>Electronic Medicines Compendium</u> website.

Reporting side effects

You should report any side effects to the Medicines and Healthcare Products Regulatory Agency, also known as the MHRA, through the Yellow Card scheme. Your doctor should also report it. You can report any side effects on the MHRA website.

"I have to cope with certain side effects, such as pain at the site of injecting and flu-like symptoms, such as headache and general achiness, but this usually subsides within a couple days. Don't be scared – it is easier than it seems at first."

Emily

Living with Ulcerative Colitis

Taking other medicines

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

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

- Prescribed medicines
- Over-the-counter medicines
- Multi-vitamins or supplements
- Herbal, complementary or alternative therapies

Medicines not to take

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

Telling other health professionals about taking adalimumab



When starting adalimumab, you should be given a patient reminder card. This contains important safety information about adalimumab. 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 adalimumab. If you stop taking adalimumab, you should still carry this card for up to 70 days after your last dose.

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 or bacteria could reproduce too much and cause a serious infection.

You should not have live vaccines while taking adalimumab.

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

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

In the UK, live vaccines include:

- BCG for tuberculosis
- Chicken pox vaccine, known as varicella
- Measles, mumps and rubella. These will be given either as individual vaccines or as the triple MMR vaccine
- Yellow fever
- Rotavirus. This is for babies only
- Nasal flu vaccine used in children. The injected flu vaccine used in adults is not live
- 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 or bacteria to close contacts who are immunosuppressed. This could then cause an infection.

For most of the live vaccines used in the UK, the virus or bacteria is not passed on to contacts. You can reduce the risk by following some simple steps, 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

It is safe to have non-live vaccines when you are taking adalimumab.

Everyone with Crohn's or Colitis taking a biologic medicine should be invited to have the flu vaccine every year. You may be advised to have the pneumococcal vaccine. You are also eligible for all doses of <u>COVID-19 vaccination</u>. These are **not** live vaccines.

People aged 50 years or older who are severely immunosuppressed also qualify for the shingles vaccine. This includes people taking a biologic, such as adalimumab. A non-live shingles vaccine, Shingrix, is available.

Pregnancy and fertility

Fertility

Adalimumab is not thought to affect male or female fertility. If you do not want to get pregnant you should use contraception.

Contraception

Your contraception will not be affected by adalimumab and will work as normal. This includes:

- The combined pill
- Progesterone-only pill
- Emergency contraception

However, if adalimumab makes you vomit, contraceptive pills may not be as effective and may not protect you from pregnancy. If you are sick, check the information that comes with your contraceptive or speak to a pharmacist.

Planning a pregnancy

Speak to your IBD team if you are offered or are taking adalimumab 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.

Adalimumab is generally considered safe to take during pregnancy. Research shows that it is not likely 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 medicines like adalimumab, during pregnancy. This includes mothers who took these medicines until birth.

It is possible for adalimumab to cross the placenta and enter your baby's blood. This may mostly 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 adalimumab and for at least five months after your last dose. They also suggest that adalimumab 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 adalimumab 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 you to take adalimumab for the first six months of your pregnancy only. This aims to reduce exposure to your baby. If your condition is not well controlled, your IBD team may recommend you take adalimumab throughout your pregnancy.

If you have an unplanned pregnancy

Contact your IBD team straight away if you are on adalimumab and find out 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 took adalimumab during your pregnancy. If you did, you may be told that your baby should not have live vaccines until they are a bit older. 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. For these vaccinations, you may need to wait until your baby is between five and 12 months old or until adalimumab cannot be found in the baby's blood. But sometimes the benefit of giving a live vaccine earlier may be greater than the potential risk.

Taking adalimumab during pregnancy should not affect the rest of your baby's <u>vaccination schedule</u>. 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 adalimumab, you should take extra care if your baby has the rotavirus vaccine. Live virus can be shed in the baby's poo for a few weeks. Make sure you wash your hands 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 adalimumab during pregnancy.

Discuss the risks and benefits of taking adalimumab 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> health.

Breastfeeding

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

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

- Normal growth
- Normal development
- Normal rates of infection

Some studies have found small amounts of adalimumab in breast milk, but it has not been found in breastfed babies. Adalimumab cannot be taken by mouth because it is broken down and destroyed in the gut. Adalimumab in breast milk is also likely to be broken down in your baby's gut, so only very small amounts may be absorbed by your baby. Speak to your IBD team if you are worried.

Drinking alcohol



You can drink alcohol while you are on adalimumab. But, just like everyone else, you should follow <u>NHS guidelines</u> on counting your weekly alcohol units to reduce general health risks.

Who to talk to if you're worried

<u>Taking medicines</u> and managing side effects can be difficult. We understand and we're here to help. <u>Our 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 other options there might be. 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 does not replace specific advice from your health professional. Talk to your GP or IBD team for information that's specific to you.

Other organisations

The Electronic Medicines Compendium. This provides up-to-date, approved and regulated prescribing and patient information for licensed medicines <u>medicines.org.uk</u>

The Medicines and Healthcare Products Regulatory Agency, also known as the MHRA. This regulates medicines, medical devices and blood components for transfusion in the UK. You can report any side effects to the MHRA through the Yellow Card scheme - Yellowcard.mhra.gov.uk

Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our information covers a wide range of topics. From treatment options to symptoms, relationship concerns to employment issues, our information can help you manage your condition. We'll help you find answers, access support and take control.

All information is available on our website.

Helpline service

Our helpline team provides up-to-date, evidence-based information. You can find out more on our <u>helpline web page</u>. Our team can support you to live well with Crohn's or Colitis.



Our Helpline team can help by:

- Providing information about Crohn's and Colitis
- Listening and talking through your situation
- Helping you to find support from others in the Crohn's and Colitis community
- Providing details of other specialist organisations

You can call the Helpline on **0300 222 5700**. You can also visit our <u>livechat service</u>. Lines are open 9am to 5pm, Monday to Friday, except English bank holidays.

You can email helpline@crohnsandcolitis.org.uk at any time. The Helpline will aim to respond to your email within three working days.

Social events and Local Networks

You can find support from others in the Crohn's and Colitis community through our virtual social events. There may also be a Local Network in your area offering in-person social events. Visit our <u>Crohn's and Colitis UK in your area webpage</u> to find out what is available.

Crohn's & Colitis UK Forum

This closed-group Facebook community is for anyone affected by Crohn's or Colitis. You can share your experiences and receive support from others. Find out more about the Crohn's & Colitis UK Forum.

Help with toilet access when out

There are many benefits to becoming a member of Crohn's & Colitis UK. One of these is a free RADAR key to unlock accessible toilets. Another is a Can't Wait Card. This card shows that you have a medical condition. It will help when you are out and need urgent access to the toilet. See our membership webpage for more information. Or you can call the Membership Team on **01727 734465**.

Crohn's & Colitis UK Medicine Tool

Our **Medicine Tool** is a simple way to compare different medicines for Crohn's or Colitis. You can see how medicines are taken, how well they work, and what ongoing checks you need. You can find out more on our **Medicine Tool webpage**.

The Medicine Tool can help you:

Understand the differences between types of medicines





- Explore different treatment options
- Feel empowered to discuss medicine options with your IBD team

Always talk to your IBD team before stopping or changing medicines.

About Crohn's & Colitis UK

Crohn's & Colitis UK is a national charity, leading the fight against Crohn's and Colitis. We're here for everyone affected by these conditions.

Our vision is to see improved lives today and a world free from Crohn's and Colitis tomorrow. We seek to improve diagnosis and treatment, fund research into a cure, raise awareness and give people hope and confidence to live freer, fuller lives.

Our information is available thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis by calling **01727 734465**. Or you can visit <u>our website</u>.

About our information

We follow strict processes to make sure our information is based on up-to-date evidence and is easy to understand. We produce it with patients, medical advisers and other professionals. It is not intended to replace advice from your own healthcare professional.

You can find out more on our website.

We hope that you've found this information helpful. Please email us at evidence@crohnsandcolitis.org.uk if:

- You have any comments or suggestions for improvements
- You would like more information about the evidence we use
- 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 you can contact us through the Helpline on 0300 222 5700.

We do not endorse any products mentioned in our information.



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Trusted Information Creator

Patient Information Forum