

# **Adalimumab**

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

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

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# **Key facts about adalimumab**

- 1. Adalimumab is used to treat Crohn's and Colitis, but it doesn't work for everyone.
- 2. You take adalimumab by injection under your skin (subcutaneous injection).
- 3. Adalimumab 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 live vaccines while taking adalimumab. You can have the yearly flu jab, as this is not live.

### Other names for this medicine

Adalimumab is also known by the brand names Amgevita, Hulio, Humira, Hyrimoz, Idacio, Imraldi and Yuflyma. It will be prescribed by brand name.

Humira was the first brand of adalimumab. Amgevita, Hulio, Hyrimoz, Idacio, Imraldi and Yuflima are 'biosimilars' of Humira but work in the same way. They are very similar to Humira with the same treatment effects. But there are some slight differences, such as how the injection device works. They also may contain different ingredients to prolong shelf-life. For more about biosimilars see our information on **biologic medicines**.

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

Thea, age 47
Living with Crohn's Disease

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#### What adalimumab is and how it works

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

Adalimumab 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. Adalimumab binds to TNF-alpha, blocking its harmful effects and reducing inflammation. This helps to relieve symptoms.

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

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

You can find out more about anti-TNF medicines by watching a video online: <a href="mailto:crohnsandcolitis.org.uk/adalimumab.">crohnsandcolitis.org.uk/adalimumab.</a>

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# Why you've been offered adalimumab

Adalimumab is used to treat:

- moderate to severely active Crohn's Disease (including Crohn's Colitis) in adults and children from 6 years of age
- moderate to severely active Ulcerative Colitis in adults

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 adalimumab 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 of needing surgery.

**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 less affected 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.

#### Adalimumab may also:

- be effective when infliximab (another anti-TNF) has not worked
- reduce the risk of Crohn's coming back after surgery
- treat fistulas in people with Crohn's. Find out more in our information on <u>Living</u>
   with a Fistula.

#### Other health conditions

Adalimumab is also to treat rheumatoid arthritis, ankylosing spondylitis, psoriasis, hidradenitis suppurativa and uveitis.

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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>Guide to Appointments</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 adalimumab is in Crohn's and Colitis

Adalimumab 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 adalimumab. 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 adalimumab 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 adalimumab 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 adalimumab for one year compared with people who had not been taking adalimumab (placebo). But, not everyone responds to adalimumab.

### After one year of treatment...

	People not taking adalimumab (placebo)	People taking adalimumab
People with their Crohn's under control (in remission)	14%	40%
People with some improvement in their Crohn's (but not in remission)	5%	5%
People who did not improve		<b>55%</b>

### If you have Ulcerative Colitis

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

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

After one year of treatment...

	People not taking adalimumab (placebo)	People taking adalimumab
People with their Colitis under control (in remission)	10%	20%
People with some improvement in their Colitis (but not in remission)	30%	<b>1111111</b> 34%
People who did not improve	60%	<b>46</b> %

# How long adalimumab takes to work

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

However, adalimumab 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.

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#### How to take adalimumab

Adalimumab is given as an injection under the skin. Adalimumab cannot be taken by mouth as a tablet because it would be destroyed by your digestive system.

Your treatment will be supervised by your IBD team. The first dose is usually given 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. 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.

#### Children

Adalimumab for children may either come as a pre-filled syringe or pre-filled pen, or in a vial (small bottle). The vial is designed to fit onto a syringe using an adapter. Only the brand Idacio comes in a vial.

#### **Delivery**

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

Adalimumab 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 adalimumab prescription, as long as you're entitled to NHS care.

### Storage

Adalimumab should be kept in the fridge. But, if you are travelling, it can be stored at room temperature (25 °C) out of sunlight for up to:

- 14 days (Amgevita, Hulio, Humira)
- 21 days (Hyrimoz)
- 28 days (Imraldi, Idacio)
- 30 days (Yuflyma).

Always check the leaflet that comes with your medicine. 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 **Travel**.

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# Tips on injecting

Make sure that you know how your injection device works. Different brands of adalimumab use different methods. For some, you'll need to pinch your skin before you inject, or you may need to press a button to inject the medicine.

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.

"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, age 55
Living with Crohn's Disease

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# What is the normal dosage?

You'll have your first induction dose followed by another induction dose two weeks later. The induction doses are higher to give a fast response. In children this may be increased to give a quicker response. You'll then have maintenance dosing every two weeks if you respond well.

If adalimumab doesn't work for you, or it becomes less effective, your doctor may suggest that you try a higher dose or dosing every week. 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. You must not make any dose changes unless your IBD team have told you to.

Dosing schedule for adults and children			Continue every 2 weeks				
	•				-		
	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Adults with Crohn's.	160mg <b>or</b> 80mg		80mg <b>or</b> 40mg		40mg		40mg
Children with Crohn's weighing over 40kg.	80mg		40mg		40mg		40mg
Children with Crohn's weighing under 40kg.	40mg		20mg		20mg		20mg
Adults with Ulcerative Colitis.	160mg		80mg		40mg		40mg
	Injection in hospital <b>or</b> nurse at home.		Injection in hospital or nurse at home or self-inject at home.		Self- inject at home.		Self- inject at home.
	Induction doses			Mair	ntenance d	oses	

You may need more than one injection for your induction doses if your adalimumab contains 40mg of the medicine.

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# How long you'll take this medicine

You are likely to have a planned course of treatment for up to a year if adalimumab 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 adalimumab is still right for you.

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# **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:

- Adalimumab is not effective if this medicine hasn't worked for you within 2-3
  months. 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 adalimumab 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.
- Adalimumab becomes less effective some people develop antibodies to adalimumab over time, which can stop it working. Your antibody levels will be checked using a blood test.
- **Issues with injecting yourself** you may prefer to try a treatment which 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, so they can 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 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 **biologic medicines**.

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# Taking adalimumab with other Crohn's or Colitis treatments

You may take adalimumab with other medicines for your Crohn's or Colitis, such as <u>5-</u> <u>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 adalimumab with azathioprine or methotrexate 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 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 adalimumab is right for you.

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. Adalimumab 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.

• Latex allergy. The needle cover of the Amgevita pre-filled pen is made from dry natural rubber (latex) and may cause an allergic reaction.

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
- you have ever had chicken pox, shingles or measles. You may be able to be vaccinated against these before you start treatment.

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# **Ongoing checks**

You'll need regular checks while taking adalimumab, 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 adalimumab 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**

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 adalimumab. See the section below on **Side effects**.

Even though your risk of complications may be higher when taking adalimumab, 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 yearly flu jab. 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. Taking azathioprine and mercaptopurine in combination with adalimumab can increase this risk. Practice good sun safety, such as wearing a hat and high factor sunscreen, staying in the shade and avoiding sunbeds. The <a href="NHS website">NHS website</a> 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 adalimumab 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.

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### **Side effects**

All medicines can have unwanted effects, although not everyone will get them. Some side effects can happen right away, others may happen later. Some can even last for a 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 injection or an allergic reaction:
  - o Hives (red, raised, itchy patches of skin) or other skin rashes
  - Trouble breathing or swallowing, or shortness of breath
  - o Pains in your chest or muscles or joints
  - Fever or chills
  - Swelling of your face, hands or feet
  - Headaches or a sore throat
- 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
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- o Feeling overly tired
- o A cough with mucus/sputum
- o Warm painful skin
- Stinging when passing urine
- An open cut or wound
- o Tooth or gum pain or swelling
- Other symptoms:
  - Bruising, bleeding or paleness
  - Changes in your vision
  - Numbness or tingling
  - Joint swelling

#### Most common side effects

Around 1 in every 10 people taking adalimumab may have:

- Injection-site reactions (redness, swelling or pain where you've injected)
- Upper respiratory tract infections (like colds, tonsilitis and sinus infections)
- Tummy pain or being or feeling sick (nausea)
- Low white blood cell count or anaemia (low iron)
- Headaches
- Skin rashes
- Muscle pain

#### Other side effects

- Infections. You may need to delay taking adalimumab if you have an infection. Ask your IBD team for advice.
  - Common: Flu, gastroenteritis, 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.

- Nervous system problems.
  - Common: Migraine or pins and needles.
  - o 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 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).
  - Uncommon: Heart failure or heart attack.
- Changes in your mental health.
  - o Common: Changes in mood, depression, anxiety or trouble sleeping.
- Liver and gall bladder problems. Tell your doctor if your skin or eyes look yellow, you feel very tired with a lack of appetite, or you have ongoing pain on the right side of your tummy (abdomen).
  - o Common: Gall bladder inflammation or gall stones.
  - Uncommon: Adalimumab can activate viral hepatitis if you carry it in your blood. Your doctor will check if you are a carrier before you start treatment.
- Skin reactions. Some of these can be treated without stopping adalimumab.
  - o Common: Psoriasis (scaly patches), eczema, bruising, alopecia.
  - Rare: Other skin conditions which can cause ulcers or blisters.
- Some types of skin cancer. You must tell your doctor if you have a bump or open sore which is not healing.
  - Uncommon: Melanoma.
- Other types of cancer. This medicine may not be right for you if you've previously had cancer.
  - Uncommon: Lymphoma (blood cancer).
  - Rare: Leukaemia (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 adalimumab may develop this side effect.	
Uncommon.	Somewhere between 1 in every 100 people to 1 in every 1000 people	
	taking adalimumab may develop this side effect.	
Rare.	Somewhere between 1 in every 1000 people to 1 in every 10,000	
	people taking adalimumab 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 <a href="medicines.org.uk/emc/">medicines.org.uk/emc/</a>.

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. Report your side effect at <a href="mailto:yellowcard.mhra.gov.uk">yellowcard.mhra.gov.uk</a>.

"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, age 21
Living with Ulcerative Colitis

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# **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'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 adalimumab. 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.

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#### **Vaccinations**

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

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 vaccine. This is not a live vaccine and is safe to have while taking adalimumab.

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**

Adalimumab 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 adalimumab and planning a pregnancy or are already pregnant. If you decide to continue taking adalimumab, it should not stop you having a normal pregnancy and a healthy baby. Research shows that anti-TNF medicines, like adalimumab, 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.

Adalimumab 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 adalimumab 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 adalimumab and for at least five months after your last dose. However, adalimumab 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 adalimumab, you should also 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), your IBD team may recommend you take adalimumab for the first six months (first and second trimesters), but stop during the third trimester. This aims to reduce the exposure to your baby. If your condition is not well controlled, your IBD team may recommend you take adalimumab throughout your entire pregnancy to keep you well.

Taking adalimumab during pregnancy is likely to affect when your baby can have any live vaccines. This includes the BCG for tuberculosis and the rotavirus vaccine. It should not affect the rest of your baby's **vaccination schedule**.

National guidance advises that if you take adalimumab during your pregnancy your baby should not have live vaccines until they are at least six months old. However, adalimumab drug companies advise that your baby should not have any live vaccines for five months after your last adalimumab dose during pregnancy.

You must tell your baby's healthcare team you were taking adalimumab while pregnant. Decisions on what vaccines your baby should have and when they should have them needs to be made on an individual basis. Your IBD team and midwife should be able to help you come to a decision.

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 mercaptopurine along with anti-TNFs, like adalimumab, during pregnancy.

Discuss the risks and benefits of taking adalimumab while pregnant with your IBD team. You can 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-TNFs. But it's generally considered safe for a man to conceive a child.

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### **Breastfeeding**

You can take adalimumab while breastfeeding. Small amounts of adalimumab have been found in breast milk, but adalimumab has not been found in breastfed babies. Adalimumab is destroyed by the digestive system when taken orally, so it wouldn't be absorbed by your baby.

Small studies of babies breastfed by mothers taking adalimumab 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 interact with adalimumab.

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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 medicines.org.uk/emc.

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# 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: <a href="mailto:crohnsandcolitis.org.uk/information">crohnsandcolitis.org.uk/information</a>

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 <a href="mailto:crohnsandcolitis.org.uk/membership">crohnsandcolitis.org.uk/membership</a> for more information, or call the Membership Team

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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 <a href="mailto:evidence@crohnsandcolitis.org.uk">evidence@crohnsandcolitis.org.uk</a> 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.

This information is available for free thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis: call **01727 734465** or visit **crohnsandcolitis.org.uk**.