

Golimumab

This information is for people with <u>Colitis</u> who are on golimumab treatment or who are thinking about starting it. This information can help you to decide if this treatment is right for you. It looks at:

- How golimumab works
- What you can expect from golimumab
- How to take golimumab
- Possible side effects
- Stopping or changing treatment

This information is about golimumab in general. It should not replace advice from your IBD team.

Contents

Key facts about golimumab	. 2
Other names for this medicine	. 2
What golimumab is and how it works	. 3
Why you might have been offered golimumab	. 3
Deciding which medicine to take	. 4
How effective golimumab is in Colitis	. 5
How quickly golimumab works	. 6
How to take golimumab	. 6
Tips on injecting	. 7
What is the normal dosage?	. 8
How long you'll take this medicine	. 9
Taking golimumab with other Colitis treatments	10
Checks before starting this medicine	10





Ongoing checks	12
Special precautions	12
Side effects	13
Taking other medicines	17
Vaccinations	18
Pregnancy and fertility	19
Breastfeeding	21
Drinking alcohol	22
Who to talk to if you're worried	22
Help and support from Crohn's & Colitis UK	22
About Crohn's & Colitis UK	24

Key facts about golimumab

- Golimumab is used to treat Colitis, but it doesn't work for everyone.
- You take golimumab by injection under your skin.
- Golimumab affects the way your immune system works. Taking this medicine may make you more at risk of infections. You may be told to take extra care.
- Tell your IBD team if you notice any side effects, or if you have signs of infection.
- You should not have live vaccines while taking golimumab. Having an annual flu
 vaccine and COVID-19 vaccination can help protect you. These are not live vaccines.

Other names for this medicine

Golimumab is known by the brand names Simponi and Gobivaz. Your medicine will be prescribed by brand name.

Simponi was the first brand of golimumab. Gobivaz works in the same way but is known as a 'biosimilar'. This means it is similar to Simponi and has the same treatment effects.



But there are some small differences in the ingredients used to keep the medicines stable. The injection devices may also look or work slightly differently.

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

What golimumab is and how it works

Golimumab 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 produced in a lab by living cells.

Golimumab targets a protein in the body called tumour necrosis factor-alpha (TNF-alpha). TNF-alpha is naturally made by your body. It plays a key role in fighting 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. Golimumab binds to TNF-alpha, blocking its harmful effects and reducing inflammation. This can help to relieve symptoms.

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

- Adalimumab used to treat Crohn's and Colitis
- Infliximab used to treat Crohn's and Colitis

Why you might have been offered golimumab

Golimumab is used to treat people over 18 years old who have moderate to severe Colitis. The aim of using this medicine is to get your Colitis under control and keep it under control. Keeping your Colitis under control is good for your long-term health. It lowers your risk of complications and need for surgery.



It may be given to you if other treatments, such as steroids or immunosuppressants, like azathioprine, mercaptopurine or methotrexate:

- Have not worked
- Have caused significant side effects
- Are not right for you

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

Golimumab is not yet licenced for Crohn's Disease. Research has found that it may help some people with Crohn's who have not responded to other anti-TNF medicines.

Other health conditions

Golimumab is also used to treat some types of arthritis.

Deciding which medicine to take

There are lots of things to think about when you start a new treatment. Your IBD team will talk to you about your options. For new treatments, you might want to think about the potential benefits, possible risks, and the goals of your treatment. 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



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

How effective golimumab is in Colitis

Golimumab can help to get your Colitis under control and keep it under control.

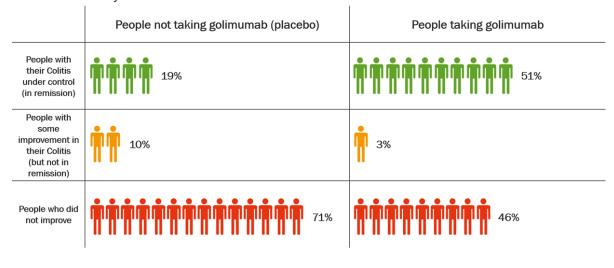
Find out more about how we talk about the effectiveness of medicines.

Golimumab in Colitis

The table below shows data from clinical trials of golimumab in adults with moderate to severe Colitis.

More than twice as many people had their Colitis under control after taking golimumab for one year, compared to people who had not been taking it. But not everyone responds to golimumab.

After one year of treatment...





How quickly golimumab works

Everyone responds differently when taking a new medicine. Some people start feeling better within 14 weeks of starting treatment with golimumab. For others, it may take longer. Golimumab might not work at all for some people.

Your IBD team may check to see how well your medicine is working for you.

How to take golimumab

Golimumab is given as an injection under the skin. It can not be taken by mouth because your stomach would break it down.

Your treatment will be supervised by your IBD team. Your first dose will usually be given in hospital, or by a trained nurse at home. You will then be trained to inject this medicine yourself. It may be possible for someone else, such as a family member, to be trained to give you your injections.

Golimumab 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 is inside. The syringes and pens come in a pack. Each pack contains an alcohol pad to clean your skin before you inject.

Delivery

A special delivery company sends your golimumab to your home. Golimumab 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 prescription if you're entitled to NHS care.

Storage

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

You can keep golimumab injections out of the fridge for up to 30 days. This might be useful if you're travelling. You must keep them in the original carton at room temperature



(up to 25°C). They must be kept out of direct sunlight. Do not put it back in the fridge. Do not use the injections if they are left out of the fridge for more than 30 days. Ask your pharmacist to get rid of any unused medicines. Find out more about travelling with medicines in our information on <u>Travelling with Crohn's or Colitis</u>.

Tips on injecting

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

- Let your medicine warm to room temperature
 It might be uncomfortable if you inject yourself with golimumab straight from the
 fridge. Take it out of the fridge about 30 minutes before you inject it. This helps it
 warm to room temperature. Do not warm the injection in any other way. Do not
 put in hot water or use a microwave.
- Choose your injection site
 Good places to inject are the stomach (away from the belly button) or upper thigh.
 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.
- Try using an ice pack before you inject
 You might find it helpful to put an ice pack on the area for 2 to 3 minutes before
 you inject. If you do this, put a thin towel under the ice pack or wrap it in a cloth.
 This can stop your skin being harmed by the cold.
- Wash your hands and clean the skin at the injection site
 Wash your hands with soap and water. Remember to clean the skin with an
 alcohol wipe before you inject yourself. This can reduce the risk of infection.
- Use a good injection technique
 Use your thumb and index finger to gently hold the skin around the sterilised area.
 Do not pinch the skin. Use one quick motion to insert the needle. Push the plunger slowly and evenly to inject all the medicine. Keep pressure on the plunger head. If you use a syringe, the injection will take about 2-5 seconds. If you use a pen this will take about 15 seconds.

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- Use an ice pack after you inject
 To help with pain after the injection, put an ice pack or cold damp towel on the
 area. Do this for about 10 to 15 minutes. Remember to put a thin towel under the
- 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.

What is the normal dosage?

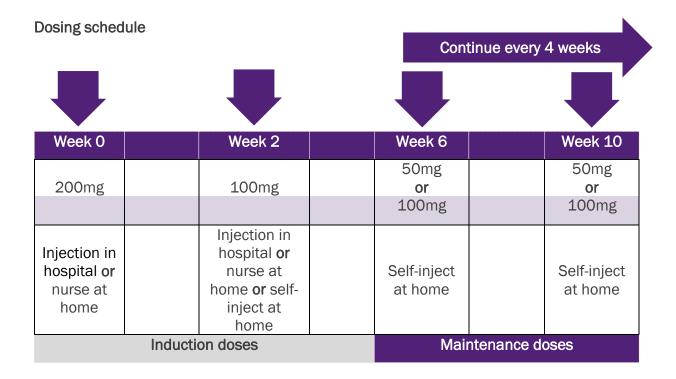
ice pack or wrap it in a cloth.

You'll have a first dose of 200mg. This will be followed by 100mg two weeks later. These higher first doses give a fast response. If you respond well, you'll have a maintenance dose every four weeks. If you weigh less than 80kg, you will usually inject 50mg every four weeks. If you weigh 80kg or more, you will inject 100mg every four weeks.

If you weigh less than 80kg and golimumab doesn't work for you, or if it becomes less effective, your doctor may ask you to try a higher dose. 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. You must not make any dose changes unless your IBD team have told you to.







You may need more than one injection pre-filled pen or syringe for your induction doses.

How long you'll take this medicine

If golimumab works well for you, you'll continue taking it for up to a year. After that, your IBD team will look at whether it still helps. If it does, you will most likely continue treatment. If you continue using it, your IBD team should assess you at least every 12 months. This is to make sure golimumab is still right for you.

Stopping or changing treatment

There are a few reasons why you and your IBD team may want to stop or change your treatment:

- Golimumab is not effective if this medicine hasn't worked for you within 3-4
 months your IBD team may stop treatment. This will depend on the practice at your
 hospital. Your IBD team may try changing your dose before suggesting you stop
 treatment.
- Your Colitis is under control if your Colitis is under control for 12 months you might be able to stop taking golimumab. If you become unwell again (relapse), you should be able to start golimumab again. Re-starting anti-TNF treatment is successful in around 3 in 4 people with Colitis.



- Side effects If you have serious side effects. You may need to stop taking golimumab If you have side effects that affect your daily life or are hard to manage.
- Golimumab stops working well some people develop antibodies to golimumab over time, which can stop it from working.
- Issues with injecting yourself you may prefer to try a treatment that involves having medication in a different way, such as by an intravenous infusion in hospital.

Do not stop taking your medicine without discussing it with your IBD team. If golimumab is no longer the best treatment for you, your IBD team should discuss other treatment options with you.

Taking golimumab with other Colitis treatments

You may take golimumab with other medicines for your 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 golimumab with azathioprine or methotrexate may be more effective. This can reduce the risk of golimumab becoming less effective over time. You should speak to your IBD team about the risk of extra side effects with combination therapy. You should decide together what the best treatment is for you.

Checks before starting this medicine

Before you start golimumab, your IBD team may ask you some questions and do some tests. This is to make sure that golimumab is right for you. Tell your IBD team if:

You have an infection, or if you are feeling unwell or feverish. You may need to
delay your treatment if you have an infection. Also, let your IBD team know if you
have often had infections in the past.



- You have ever had tuberculosis (TB) or you have recently been in close contact
 with someone who has TB. If you have TB, it will need to be treated before you
 start golimumab. You will usually have a blood test or a chest X-ray to check for TB.
- You have HIV or hepatitis (a liver infection caused by a virus). You will usually have a blood test to check for these viruses.
- You have cancer, have had cancer or have a family history of cancer. Golimumab
 affects how your immune system works and may increase the risk of some types of
 cancer.
- You have a heart condition. Your heart will need to be monitored closely before, during, and after treatment.
- You have had chickenpox, shingles, cold sores or genital herpes. You may be able
 to be vaccinated against these before you start treatment.
- You have any other 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.
- You have a condition or take any other medicine that weakens your immune system.
- You have a latex allergy. The needle cover of the Simponi pre-filled pen or pre-filled syringe is made from rubber containing latex. It may cause an allergic reaction.
 However, the needle cover of Gobivaz pre-filled devices does not contain latex.

And tell your IBD team if:

- You smoke
- You are pregnant, planning to get pregnant or breastfeeding
- You are taking any other medicines
- You've had any vaccinations recently, or plan to have any
- You've 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've ever had chicken pox or measles. If you've not, you may be able to be vaccinated against these before you start treatment



Ongoing checks

After you start golimumab, you should have regular checks. These are to see how well it's working and to check for any side effects. It's important that you tell your IBD team about any new symptoms or side effects as soon as they occur.

After 12 months of treatment, your IBD team should give you a check-up to see whether you should continue having golimumab. Based on your symptoms they might recommend that you continue treatment. If your condition is in complete remission, they may discuss stopping golimumab. See our section on **Stopping or changing treatment** for more information.

Special precautions

Do not drive or use any tools or machines if you become dizzy or tired after taking this medicine.

This medicine affects the way your <u>immune system works</u>. Your immune system is still able to fight off infections, just not quite as well as other people. 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 golimumab. See the section below on **Side effects**.

Even though your risk of complications may be higher when taking golimumab, it shouldn't stop you from living life as before. There are a few extra precautions your IBD team may recommend that you take. These can help to keep you safe and reduce your risk:

Have annual vaccinations. Annual flu and COVID-19 vaccinations may help to
protect you against becoming infected. 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, tuberculosis (TB) and pneumococcal disease,
 or other serious infections. Tell your IBD team if you meet 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). Take extra care to do this before eating and after using public transport. Try to avoid touching your face when your hands are not clean.
- Practice good food hygiene. You may be at risk of more severe infections caused
 by bacteria found in food, 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. Also, if you take golimumab in combination with azathioprine and mercaptopurine it can also increase this risk. Practice good sun safety, such as wearing a hat and high-factor sunscreen, staying in the shade, and avoiding sunbeds. The NHS website has more tips for staying safe in the sun.
- Attend routine screening for cervical cancer (previously known as the smear test),
 if appropriate to you. Abnormal cell changes in the cervix are caused by the
 human papillomavirus (HPV). If you are immunosuppressed, you are more likely to
 have these abnormal cell changes. However, there is no evidence linking cervical
 cancer to the use of golimumab or other biologics. There's no need to be tested
 more regularly than other people. You'll be invited to routine screening by your GP.

Side effects

Patient alert card

When you start taking golimumab your healthcare professional should give you a Patient Alert Card. This card has important information that you and any healthcare professionals who treat you should be aware of. Always keep the Alert Card with you while you are taking golimumab. Make sure you show the card to anyone involved in your care or treatment. This includes pharmacists, dentists or A&E doctors. If you do not have a Patient Alert Card, ask your IBD team for one.



Types of side effects

All medicines can have side effects, but not everyone gets them. Some side effects can happen right away, others may happen after you have been taking golimumab for a while. Some side effects are mild and may go away on their own, or after you stop taking golimumab. Others may be more serious, could need treatment or may be long-lasting. Some side effects might mean that golimumab is not right for you. You may be more likely to have certain side effects if you receive the 100 mg dose compared with the 50 mg dose.

Speak to your IBD team if you experience 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

Up to 1 in every 10 people taking golimumab might have an allergic reaction. But serious allergic reactions are very rare.

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

Signs to look out for include:

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



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

Infections

If you take golimumab, you may get infections more easily. This is because golimumab can affect your immune system. You might get more infections than you are used to. Or if you get an infection, it might last longer or be more serious than usual. Sometimes, previous infections can reappear, such as Tuberculosis or Hepatitis B virus.

Tell your doctor or IBD team immediately if you develop:

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

- Feeling feverish, generally being unwell or having flu-like symptoms
- Feeling overly tired
- A persistent cough with mucus or phlegm
- Shortness of breath
- Diarrhoea
- Warm painful skin
- Stinging when passing urine
- Swelling or pain around a cut or a wound
- Tooth or gum pain or swelling

Most common side effects

Around 1 in every 10 people taking golimumab may have upper respiratory tract infections (like colds, with symptoms including a sore throat, hoarseness, and a runny or blocked nose).

Other side effects

In this section, we talk about side effects as being 'common', 'uncommon' and 'rare'. To find out what these terms mean, you can look in the table below.



- Changes in your mental health.
 - o Common: Depression or trouble sleeping.
- **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's causing your symptoms.
 - o Common: Tummy pain, feeling sick (nausea) or indigestion.
 - Uncommon: constipation, reflux
- Nervous system problems.
 - o Common: Dizziness, headaches, or pins and needles.
 - o Uncommon: problems balancing
 - 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: Anaemia (low iron) or your body may not make enough of the blood cells that help fight off infections.
 - Uncommon: Your body may not make enough of the blood cells that help to stop bleeding or may not make enough of all three different types of blood cells.
- Liver 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: Changes in liver enzymes.
 - Rare: Golimumab can activate viral hepatitis if you carry it in your blood.
 Your doctor will check if you are a carrier before you start treatment.
- **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.
 - Uncommon: An abnormal heart rhythm or coronary heart disease.
 - o Rare: New or worsening heart failure.
- Skin reactions. Some of these can be treated without stopping golimumab.
 - Common: Rash, itch, eczema or hair loss.
 - Uncommon: Psoriasis (new or worsening) or other skin conditions that 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.
 - o Rare: Melanoma.
- Other types of cancer. This medicine may not be right for you if you've previously had cancer. Cancer can also occur even if you do not have a history of it.
 - Rare: Lymphoma or leukaemia, which are both types of blood cancer. Skin cancer.
 - Not known: A rare and serious cancer called hepatosplenic T-cell lymphoma (HSTCL). HSTCL has been reported in some people taking anti-TNF medicines in combination with azathioprine or 6-mercaptopurine. The risk has not been measured – but it is a rare cancer.





How common are these side effects?

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

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

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

Taking other medicines

Golimumab is often taken alongside other medicines safely. See the earlier section **Taking golimumab with other Colitis treatments.**

However, golimumab 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 or medicines that you buy yourself and any herbal, complementary, or alternative medicines or therapies.

Do not take medicines that have 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 golimumab. Always carry the alert card that comes with this medicine. You should carry this all the time while you're taking golimumab and for up to six months after your last dose.



Vaccinations

It's not safe to have 'live' vaccines while taking golimumab. This is because live vaccinations can, in some situations, cause severe infections in immunocompromised individuals.

The current recommendation is not to have live vaccines while taking golimumab.

- If you have had a live vaccine, you will probably be told to wait at least 4 weeks before starting golimumab.
- You will probably be told to not have a live vaccine until at least 3 months after your last dose of golimumab. But you may be advised to wait longer.

Ask your IBD team to make sure your vaccinations are up to date before you start golimumab, or if you're planning to travel.

In the UK, live vaccines include:

- BCG (tuberculosis)
- Chickenpox (varicella)
- Measles, mumps and rubella (either as individual vaccines or as the triple MMR vaccine)
- Yellow fever
- Rotavirus (babies only)
- Nasal flu vaccine used in children the injected flu vaccine used in adults is not live.
- Shingles vaccine (Zostavax) a non-live shingles vaccine (Shingrix) is available for people with severe immunosuppression.
- Oral typhoid vaccine. The injected typhoid is not.

Everyone with Crohn's or Colitis taking a biological medicine should have the yearly flu vaccine and COVID-19 vaccine. These are not live vaccines and are safe to have while taking golimumab.



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 weakened form of the virus to close contacts who are immunosuppressed. This could then cause an infection. For most of the live vaccines used in the UK the virus is not passed on to contacts. You can reduce the risk by following simple precautions such as:

- Careful hand washing before direct contact with the 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.

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

Non-live vaccines

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

Pregnancy and fertility

Fertility

Golimumab has not been found to affect fertility. Speak to your IBD team if you are thinking of trying for a baby.

Pregnancy

Manufacturers advise that people who could get pregnant should use effective contraception while taking golimumab. This is to prevent pregnancy. They recommend carrying on using contraception for at least 6 months after your last injection of golimumab.



There is a moderate amount of research that looks at the use of golimumab during pregnancy. From the information available, golimumab does not seem to cause problems during pregnancy or to babies exposed during pregnancy.

Experts agree that taking golimumab while you are pregnant is probably a low risk. But, there hasn't been enough research to rule out the possibility completely. To be cautious, drug companies say that golimumab should only be used during pregnancy if needed to keep your condition under control. During pregnancy, it's important to keep your condition under control. Stopping golimumab may increase your risk of a flare-up. Your IBD team may advise that the safest option is for you to keep taking it even during pregnancy. Having active Crohn's or Colitis while pregnant can lead to premature (early) birth, low birth weight and higher rates of miscarriage.

If you take golimumab during pregnancy, your baby may temporarily have a higher risk of getting an infection. It's important that you tell your baby's doctors and other health care professionals if you took golimumab during pregnancy. It's particularly important to tell them before your baby receives any vaccines (see your baby and live vaccines).

Your baby may be more prone to infections if you take azathioprine or mercaptopurine along with anti-TNFs, like golimumab, during pregnancy.

You and your IBD team should discuss whether the benefits of taking Golimumab outweigh any risks to you and your baby.

Your baby and live vaccines

Taking golimumab during pregnancy may affect when your baby can have live vaccines. This includes the BCG for tuberculosis and the rotavirus vaccine. It should not affect the rest of your baby's <u>vaccination schedule</u>.

If you take golimumab during pregnancy, you may be told that your baby should not have live vaccines until they are a bit older. National guidelines state that you may need to wait until your baby is between 6 and 12 months old. Drug manufacturers that produce golimumab recommend you wait until six months after your last golimumab dose during pregnancy. But sometimes the benefit of giving a live vaccine earlier might be greater than the potential risk.



You must tell your baby's healthcare team you were taking golimumab while pregnant. 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 come to a decision.

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

- If you're taking golimumab and you're pregnant or planning to get pregnant, talk to your IBD team. They can discuss your treatment options with you.
- Having a flare-up during pregnancy can lead to problems. So it's a balance between keeping your condition under control and keeping any risk to your baby as low as possible.
- If you take golimumab during pregnancy, healthcare professionals may recommend
 delaying your baby's live vaccines until they are 6 to 12 months old. It's important
 to tell your baby's healthcare team that you were taking golimumab when you were
 pregnant. Decisions on whether and when your baby should have live vaccines
 should be made on an individual basis. See our information on Pregnancy and
 breastfeeding for more on your baby's live vaccines.

Breastfeeding

Most experts feel that golimumab is OK to use while breastfeeding. Small amounts of golimumab have been found in breast milk in animal studies, but golimumab hasn't been found in human breast milk. Molecules of golimumab are large, so the amount that may go into breastmilk is thought to be low. Medicines like golimumab are broken down and destroyed by your gut. Golimumab in breastmilk is likely to be broken down in your baby's gut when they feed. So very little will be absorbed by your baby.

There is very little information about taking golimumab during breastfeeding. Because there is not much information, the drug company that makes golimumab advises that



you stop taking it for at least six months before you start breastfeeding. But experts agree that golimumab is unlikely to be harmful to your baby. Tell your IBD team if you are thinking about breastfeeding while taking golimumab. They can help you weigh up the benefits of breastfeeding during treatment against any possible risks.

Drinking alcohol

Alcohol is not known to have any interaction with golimumab.

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.

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 has the information you need to help you manage your condition.





We have information on a wide range of topics, from individual medicines to coping with symptoms and concerns about relationships and employment. We'll help you find answers, access support and take control.

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

Our Helpline is a confidential service providing information and support to anyone affected by Crohn's or Colitis.

Our team can:

- Help you understand more about Crohn's and Colitis, diagnosis and treatment options
- Provide information to help you live well with your condition
- Help you understand and access disability benefits
- Be there to listen if you need someone to talk to
- Help you to find support from others living with the condition

Call us on 0300 222 5700 or email helpline@crohnsandcolitis.org.uk.

See our website for LiveChat: crohnsandcolitis.org.uk/livechat.

Crohn's & Colitis UK Forum

This closed-group community on Facebook is for everyone affected by Crohn's or Colitis. You can share your experiences and receive support from others at:

facebook.com/groups/CCUKforum.

Help with toilet access when out

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

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not



intended to replace advice from your doctor or other professional. We do not endorse any products mentioned.

About Crohn's & Colitis UK

We are Crohn's & Colitis UK, a national charity fighting for improved lives today – and a world free from Crohn's and Colitis tomorrow. To improve diagnosis and treatment, and to fund research into a cure; to raise awareness and to give people hope, comfort and confidence to live freer, fuller lives. We're here for everyone affected by Crohn's and Colitis.

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

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

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

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



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Patient Information Forum