



## INFORMATION SHEET

# GOLIMUMAB

### INTRODUCTION

This information sheet is a brief overview of some important points about golimumab for the treatment of Ulcerative Colitis. It is about golimumab in general and is not intended to replace specific advice from your doctor or any other health professional. For further information, please talk to your doctor or specialist IBD team or look at the information sheet supplied with your medication, or from the website: [www.medicines.org.uk](http://www.medicines.org.uk).

### OTHER NAMES FOR THIS MEDICINE

Golimumab is a biological drug, meaning it originates from a natural source rather than a mixture of chemicals. It is also known by the brand name Simponi.

### WHY AM I BEING TREATED WITH GOLIMUMAB?

Golimumab can be used to treat moderately to severely active Ulcerative Colitis in adults. It may be considered a suitable treatment when other drugs have not worked or have caused major side effects. It is not currently licenced for Crohn's Disease, although some people have found it effective.

### HOW DOES IT WORK?

Golimumab is made from a synthetic (man-made) antibody. It belongs to a group of medicines called 'anti-TNF' drugs or therapies. This is because it works by targeting a protein in the body called tumour necrosis factor-alpha, often abbreviated to TNF-alpha. Your body naturally produces TNF-alpha as part of its immune response, which helps fight infections by temporarily causing inflammation in affected areas. Overproduction of this protein is thought to be partly responsible for the type of chronic inflammation found in the digestive system of people with Inflammatory Bowel Disease (IBD). Golimumab binds to TNF-alpha, helping to reduce inflammation and relieve symptoms.

### HOW LONG WILL IT TAKE TO WORK?

People react differently to medication, and golimumab doesn't work for everyone. You may begin to feel better within a few days, though for some people it can take up to a few months after the first treatment session before they notice an improvement.

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Golimumab has changed my life. I began to see an improvement within a week and was able to go back to work full time and live a pretty normal life – sometimes even forgetting I had UC.

”

**Kerry**, age 39  
diagnosed with Ulcerative Colitis in 2001

“

Using the pre-loaded pen was very simple, more practical than having infusions. I never felt the needle, just a minor pain when the drug was injected. It helps to sit comfortably so you're more relaxed when injecting.

”

**Michelle**, age 30  
diagnosed with Ulcerative Colitis in 2013

“

I have Crohn's Colitis and only weigh 55kg, but I'm having the 100mg dose because of the severity and complexity of my case.

Injecting soon becomes second nature. Just make sure you take note of the date that you inject and when your next one is due, it can be very easy to forget, especially as it's in 4 week intervals.

”

**Izzy**, age 18  
diagnosed with Crohn's Colitis in 2009

## HOW DO I TAKE GOLIMUMAB?

Golimumab is given as a subcutaneous injection, which is an injection under the skin. It cannot be taken as a tablet because your digestive system would destroy it.

A nurse will give you the injections to begin with, and will train you to do the injections yourself when you are ready. This may be done by your IBD nurse, or by a nurse arranged through the delivery company that will deliver the golimumab directly to your home at a convenient time each month. If you prefer, it may be possible for someone else, such as a family member or a friend, to be trained to give the injections.

Golimumab comes ready to use in either a pre-filled syringe or a pre-filled injection 'pen'. It should always be stored in the fridge, ideally on the middle shelf and not touching the back or sides of the fridge. The syringes or pens come in a pack, which also contains an alcohol pad for cleaning the skin before injecting. The injection is usually given under the skin of your thigh or stomach, but not in the area around your stomach button or navel. It should not be given in any area where the skin is reddened, bruised or hard, and a new injection site should be at least 3cm away from any previous injection sites. If you use a syringe the injection will take about 2-5 seconds. If you use a pen it will take about 10 seconds.

## TIPS ON INJECTING GOLIMUMAB

One of the most common side effects of golimumab injections is pain at the injection site, sometimes with redness, itching and swelling. Using the drug when it is at room temperature may help reduce this, so try taking it out of the fridge about 30 minutes before you need it. Do not warm the injection in any other way, such as in hot water or a microwave. You could apply an ice pack for two or three minutes to the area you are going to inject, before cleansing the skin with the alcohol wipe.

Some people who use the syringe form find it makes it less painful if they insert the needle quickly in a single motion and then inject the medicine slowly. If your skin hurts or is swollen at the injection site after you have the injection, it may help to apply an ice pack or cold damp towel to the area for about 10-15 minutes. If you do use an ice pack, place a light towel between it and your skin.

## WHAT IS THE NORMAL DOSAGE?

When you first start taking golimumab, you will be given a starting dose of 200mg, followed by 100mg two weeks later.

After this induction treatment, you will inject your golimumab 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.

## HOW LONG WILL I BE TAKING IT?

If you respond well to golimumab, you may be put onto a planned course of treatment lasting up to a year or longer. Your treatment plan will be reassessed at least every 12 months to check whether continuing with golimumab is still right for you. If you are in stable remission, it may be decided that you can stop taking golimumab. If after stopping treatment you become unwell again, you should have the option to restart golimumab. You may also be taken off golimumab if you have serious side effects or if you have not responded strongly enough within 8 weeks.

## IS GOLIMUMAB USED IN COMBINATION WITH OTHER DRUG TREATMENTS FOR IBD?

Golimumab is sometimes given in combination with steroids to help bring on remission and allow the steroid treatment to be reduced. Golimumab may also be given in combination with immunosuppressants such as azathioprine. See our information sheet on **Taking Medicines** for more information on taking more than one medicine, which is known as combination therapy.

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## HOW EFFECTIVE IS GOLIMUMAB?

Golimumab is used to treat a range of conditions including Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis as well as Ulcerative Colitis.

Although not everyone will respond to golimumab, it has been shown to be effective in treating UC, resulting in improvement of symptoms as well as healing of the intestines for some people. It can help to reduce the need for hospitalisation and surgery, and may mean that you do not have to take steroids.

People who have never tried other anti-TNF drugs (such as infliximab or adalimumab) before may respond better to golimumab. Even so, golimumab can be effective for people who have tried these drugs before.

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## WHAT CHECKS WILL I NEED?

Before you start treatment, it is important to be screened to make sure golimumab is right for you. Make sure the doctors treating you know:

- of any surgeries you have had
- of any allergies you have
- about any other medications you are taking and any recent vaccinations.
- if you have any history of tuberculosis (TB) or any exposure to people with TB. You should not be given golimumab if you have active TB, and if you have underlying, inactive TB, this will need to be treated before starting golimumab. Most doctors now use a blood test and a chest x-ray to check for underlying or inactive TB.
- If you travel to regions of the world where TB or fungal infections, such as histoplasmosis, coccidiomycosis or blastomycosis are common.
- if you have had kidney, liver, or significant heart disease.
- if you are pregnant or planning to get pregnant, or are breastfeeding.
- if you have or have ever had hepatitis B, are a carrier of hepatitis B, or have been in close contact with someone who has hepatitis B. You will usually have a blood test to check for this virus before starting golimumab. You may also be tested for HIV
- If you have ever been diagnosed with lymphoma or have had cancer recently
- if you smoke, have COPD (Chronic Obstructive Pulmonary Disease) or have severe persistent asthma
- if you have or have not been exposed to chicken pox in the past. If you have not had chicken pox, you may be able to be vaccinated against it before you start golimumab
- if you have ever been diagnosed with multiple sclerosis

## WILL I NEED ONGOING CHECKS?

Once your treatment has started your IBD team will continue to follow up with you regularly, and you may need additional blood tests. This can help to make sure that any complications are prevented or caught at an early stage. It is also important that you tell your doctor or the hospital team monitoring your treatment about any new symptoms you notice, whenever they occur.

Your treatment will be assessed every 12 months to make sure golimumab is still right for you. This may include blood tests, stool tests and endoscopies to check how active your disease is.

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## WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE BEING TREATED WITH GOLIMUMAB?

Your doctor will give you a Patient Alert Card, which contains important safety information you need to be aware of before and during your treatment with golimumab. In addition:

- Contact your doctor or the hospital if you begin to feel unwell and think you may have an infection. If you have an active infection, you should wait until this has cleared up before taking your golimumab.
- You may be at greater risk of becoming more seriously ill from viruses and bacteria such as those that cause chickenpox and shingles, measles, and pneumococcal disease. Tell your doctor if you come into contact with anyone with these conditions, even if you do not feel unwell.
- Try to avoid eating raw eggs or undercooked pate, meat and poultry, as well as unpasteurised dairy products. You may be more open to the type of infections caused by bacteria such as listeria when being treated with golimumab.
- You will be advised to have an annual flu vaccine while on golimumab treatment. You may also wish to consider having the pneumococcal vaccine every 3-5 years.
- In people taking golimumab for conditions other than IBD, there has been a reported increased risk of skin reactions, and in rare cases skin cancer. You may wish to take extra precautions when in the sunlight, for example wearing a hat and sunscreen with an SPF of at least 15.

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## WHAT ARE THE MOST LIKELY SIDE EFFECTS OF GOLIMUMAB?

Like all drugs, golimumab can have side effects, although not everybody will get them. Some side effects can happen almost immediately, while others may develop later. It can take up to six months after the last dose for golimumab to completely leave the body, so some effects might appear even after stopping treatment.

Some possible golimumab side effects are likely to be quite mild and may go away on their own. Others can be more serious and will require treatment, or may mean that golimumab is not suitable for you.

Some of the main side effects and symptoms are described on the next page.

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The only side effect I got was a headache the next day, which eased with paracetamol.

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**Michelle**, age 30  
diagnosed with Ulcerative Colitis in  
2013

### IMMEDIATE REACTIONS

- Reactions to the skin at the site of the injection, such as redness, hardness, pain, bruising, itching, tingling and irritation. This can be very common, affecting up to one in 10 people. Using golimumab when it is at room temperature or cooling your skin with an ice pack may help. (See **Tips on injecting golimumab**). Your doctor or IBD nurse should also be able to advise you on how to reduce this sort of reaction.
- Symptoms that mean you are having an allergic reaction to golimumab. For example, rashes, hives (a raised itchy rash that appears on the skin), a swollen face, hands and feet, or trouble breathing and shortness of breath.

### OTHER SIDE EFFECTS

It is common for people taking golimumab to develop upper respiratory tract infections, a sore throat or a runny nose. Other common side effects include:

- Cold sores and mouth ulcers
- Nausea
- Superficial fungal infections
- Headache
- Indigestion and stomach pain
- Feeling weak or numb
- Sinus infections
- Depression
- High blood pressure

In rare circumstances, people can develop more serious side effects to golimumab. Many of these are reversible if the drug is stopped. These include demyelination (damage to nerves), inflammatory conditions such as lupus, tuberculosis, nervous system diseases such as multiple sclerosis, heart failure, and in exceptional cases, cancer of the blood, skin or lymph nodes.

Seek medical advice immediately if you develop any of the following symptoms:

- Swelling of the face, lips, mouth, throat or feet
- Difficulty swallowing or breathing
- Fatigue, cough, weight loss or flu-like symptoms
- Changes in your vision
- Numbness or tingling
- Persistent fever, bruising, bleeding or paleness
- Weakness in your arms or legs
- Night sweats
- A burning feeling when urinating
- Dark brown-coloured urine

You should let your doctor or IBD nurse know about any new symptoms you develop while on golimumab, whenever they occur. Your IBD team should also be able to help with any queries and concerns.

This is not a complete list of side effects for golimumab. For more information see the Patient Information Leaflet provided with your medication, or visit [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc).

The Medicines and Healthcare Products Regulatory Agency (MHRA) has a Yellow Card scheme to encourage people to report any suspected side effects they experience from medicines. Visit [www.mhra.gov.uk](http://www.mhra.gov.uk) to find out more.

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I had no side effects from golimumab, only benefits – I found my skin was much less ‘spotty’ and wasn’t as prone to breaking down as it had previously. I also felt like I had a renewed energy.

Unfortunately because my previous migraines made a new appearance along with some other neurological symptoms, I was taken off treatment after two years. Although it was unlikely to be related to the golimumab, as a precaution it had to be stopped.

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**Kerry**, age 39  
diagnosed with Ulcerative Colitis in 2001

## CAN I HAVE IMMUNISATIONS WHILE ON GOLIMUMAB?

It may be unsafe to be immunised with certain vaccinations while on golimumab. You should not have any 'live' vaccines such as those for polio, yellow fever, rubella (German measles), BCG (tuberculosis) and MMR (measles, mumps and rubella). However, you may be able to have the inactivated polio vaccine.

Flu jabs are safe as they are not live vaccines, and the Department of Health recommends that everyone on drugs such as golimumab should have an annual flu vaccination. However, the nasal spray used for children's vaccines is live, and should not be used.

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## IS IT SAFE TO TAKE OTHER MEDICINES ALONG WITH GOLIMUMAB?

Golimumab may interact with certain other drugs. It should not be taken with medicines that contain the active substances anakinra or abatacept, which are commonly used for Rheumatoid Arthritis. You should also check with your doctor if you are taking any other medications that affect your immune system.

Talk to your doctor if you are unsure about whether any medicines you are taking - or are planning to take - may interact with golimumab. This includes any over the counter medicines and any herbal, complementary, or alternative medicines or therapies. You should also tell any other doctor, dentist or health professional treating you that you are being treated with golimumab.

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## DOES GOLIMUMAB AFFECT PREGNANCY?

If you're taking golimumab and thinking of starting a family or becoming pregnant, discuss this with your IBD team. The evidence about the safety of golimumab during pregnancy is limited, with most research focusing on anti-TNF drugs in general. However, the research is very reassuring, with no evidence of harm to mother or baby.

As there is not yet much clear evidence about golimumab in particular, the manufacturers recommend that if you have the potential to become pregnant, you should use adequate contraception to prevent pregnancy while you are on golimumab and for at least 6 months after stopping golimumab. Your doctor may consider alternative medications for you during pregnancy.

However, most doctors consider that if golimumab is keeping your IBD in check, it may be better to continue with it, at least until the end of the second trimester (the sixth month of pregnancy).

There is less evidence for those wanting to father a child while on anti-TNF drugs, but it is thought that it is safe for a man to conceive a child.

See our information sheets **Pregnancy and IBD** and **Fertility and IBD** for more details.

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## WHAT ABOUT AFTER THE BABY IS BORN?

As small quantities of golimumab are found in breast milk, the manufacturers recommend that you should be off the drug for at least six months in order to start breastfeeding. However, most doctors consider that if golimumab is keeping your IBD in check, there is no significant risk to breastfeeding. You should discuss this with your IBD team. If you received golimumab during your pregnancy, it is important that you tell your baby's doctor about your golimumab use before the baby receives any vaccination.



## CAN I DRINK ALCOHOL WHILE TAKING GOLIMUMAB?

Alcohol is not known to have any interaction with golimumab, but for general health reasons it is best to keep within the Department of Health guideline limits.

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## WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried or have any questions about your golimumab treatment, contact your doctor or IBD nurse. They should be able to help you with queries such as why it has been prescribed, what the correct dose and frequency are, what monitoring is in place, and what alternatives may be available for you.

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## HELP FROM CROHN'S AND COLITIS UK

We offer more than 45 publications on many aspects of Inflammatory Bowel Disease. You may be interested in our comprehensive booklet on Ulcerative Colitis, as well as the following publications:

- Biologic Drugs
- Azathioprine and Mercaptopurine
- Taking Medicines
- Living With IBD

All publications are available to download from [www.crohnsandcolitis.org.uk/publications](http://www.crohnsandcolitis.org.uk/publications). If you would like a printed copy of a booklet or information sheet, please contact our helpline - a confidential service providing information and support to anyone affected by Inflammatory Bowel Disease. Our team can:

- help you understand more about IBD, diagnosis and treatment options
- provide information to help you to live well with your condition
- help you understand and access disability benefits
- be there to listen if you need someone to talk to
- put you in touch with a trained support volunteer who has a personal experience of IBD

Call us on 0300 222 5700 or email [info@crohnsandcolitis.org.uk](mailto:info@crohnsandcolitis.org.uk)  
See our website for Live Chat: [www.crohnsandcolitis.org.uk/livechat](http://www.crohnsandcolitis.org.uk/livechat)

### **Crohn's and Colitis UK Forum**

This closed-group community on Facebook is for everyone affected by IBD. You can share your experiences and receive support from others at [www.facebook.com/groups/CCUKforum](http://www.facebook.com/groups/CCUKforum).

### **Crohn's and Colitis UK Patient Panels**

IBD Patient Panels, which are supported by Crohn's and Colitis UK, are groups of people with Inflammatory Bowel Disease who use their perspectives as patients to work with their IBD healthcare team to help improve hospital services. Visit the Crohn's and Colitis UK website for further information or email [patientinv@crohnsandcolitis.org.uk](mailto:patientinv@crohnsandcolitis.org.uk).

### **Crohn's and Colitis UK Local Networks**

Our Local Networks of volunteers across the UK organise events and provide opportunities to get to know other people in an informal setting, as well as to get involved with educational, awareness-raising and fundraising activities. You may find just being with other people and realising that you are not alone can be reassuring. Families and relatives may also find it useful to meet other people with IBD. Visit [www.crohnsandcolitis.org.uk/membership](http://www.crohnsandcolitis.org.uk/membership) to become a member and find your Local Network.

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[publications@crohnsandcolitis.org.uk](mailto:publications@crohnsandcolitis.org.uk). You can also write to us at Crohn's and Colitis UK, 45 Grosvenor Road, St Albans, AL1 3AW or contact us through the **Information Line: 0300 222 5700**.

### ABOUT CROHN'S & COLITIS UK

We are a **national** charity established in 1979. Our aim is to improve life for anyone affected by Inflammatory Bowel Diseases. We have over 35,000 members and 50 Local Networks throughout the UK. Membership starts from £15 per year with concessionary rates for anyone experiencing financial hardship or on a low income.

This publication is available free of charge, but we would not be able to do this without our supporters and members. Please consider making a donation or becoming a member of Crohn's and Colitis UK. To find out how call **01727 734465** or visit [www.crohnsandcolitis.org.uk](http://www.crohnsandcolitis.org.uk)

