



Mirikizumab

This information is for people with <u>Crohn's Disease</u> or <u>Ulcerative Colitis</u> who are taking mirikizumab, or are thinking about starting it. Mirikizumab is also known by the brand name Omvoh. This information can help you to decide if mirikizumab is right for you. It looks at:

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

This information is about mirikizumab in general. It should not replace advice from your IBD team. Talk to your IBD team or read the leaflet that comes with your medicine for more details. You can also find out more about your medicine at medicines.org.uk.

At the moment, mirikizumab is not recommended for people with Microscopic Colitis. Where we use the term 'Colitis' in this information, we are referring to Ulcerative Colitis.

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Key facts about mirikizumab

- Mirikizumab is used to treat Crohn's Disease and Ulcerative Colitis in adults. It can help get your symptoms under control and keep them under control.
- It is usually an option if other treatments have not worked or have stopped working.
 You might also have it if other treatments have caused serious side effects or are not suitable for you.
- To begin with, you will have mirikizumab through a drip into a vein in your arm. If you respond well, you will carry on having it as an injection under your skin.
- Mirikizumab alters your immune system. So your body might not be able to fight off
 infections as well as it used to. Contact your GP or IBD team straight away if you
 think you have an infection.
- You should not have live vaccines when you are taking mirikizumab. You can have non-live vaccines, like the yearly flu injection and COVID-19 vaccines.
- Talk to your IBD team if you are taking mirikizumab, or thinking about taking it, and you are pregnant or planning to get pregnant. They can discuss your treatment options with you.

Other names for mirikizumab

Mirikizumab is also known by the brand name Omvoh.

Mirikizumab is one of a group of medicines called <u>biologics</u>. Biologic medicines are antibodies that are made by living cells in a lab. Antibodies are proteins that recognise and stick to specific targets. The antibodies that are part of your own natural defence system may stick to and target harmful substances such as bacteria or viruses. Antibodies that are made in a lab mimic your body's natural ability to fight off harmful substances.





How does mirikizumab work?

Mirikizumab is an interleukin inhibitor. Interleukins are proteins that have an important role in controlling your immune system. Your immune system is your body's natural defence system. Mirikizumab blocks interleukin-23 (IL-23). IL-23 has a key role in long-term inflammation in the gut. So, by blocking IL-23, mirikizumab reduces some of the inflammation that causes the symptoms of Crohn's and Colitis.

Why you might be offered mirikizumab

Mirikizumab is used to treat adults who have:

- Moderate to severe Ulcerative Colitis.
- Moderate to severe Crohn's Disease

It aims to get your Crohn's or Colitis under control and keep it under control.

Your IBD team might suggest mirikizumab for you if you have Crohn's or Colitis and:

- Standard treatments or an anti-TNF or other biologic medicine have not worked well enough
- Standard treatments or an anti-TNF or other biologic medicine have stopped working
- You had to stop standard treatments or an anti-TNF or other biologic medicine because you had bad side effects
- You cannot have standard treatments or anti-TNF medicines for other medical reasons

Standard treatments vary depending on the condition you have, but may include <u>aminosalicylates</u>, oral <u>steroids</u> or <u>immunomodulators</u> like <u>azathioprine or mercaptopurine</u>. Anti-TNF medicines include <u>infliximab</u>, <u>adalimumab</u>, and <u>golimumab</u>. Other biologics include <u>risankizumab</u>, <u>ustekinumab</u> and <u>vedolizumab</u>, as well as anti-TNF medicines.

Other medicines used for Crohn's or Colitis include JAK inhibitors, such as <u>tofacitinib</u>, <u>filgotinib</u> and <u>upadacitinib</u>, and sphingosine 1 phosphate receptor modulators, such as <u>ozanimod</u> and <u>etrasimod</u>.





Deciding which medicine to take

There are lots of things to think about when you start a new treatment. Your IBD team will discuss your options with you. They might give you a choice of different treatments. You should consider the potential benefits, possible risks, and the goals of your treatment together. Things to consider include:

- How you take it
- · How often you take it
- · How effective it is
- How quickly it's likely to work
- · How long it's likely to keep working
- Side effects that you might get
- Whether you need ongoing tests or checks
- Other medicines you are taking
- If you are planning to get pregnant

You could use our <u>Medicine Tool</u> to help you think about your options. Our <u>Appointment</u> <u>guide</u> includes a list of questions you might want to ask your healthcare professional. This can help you focus on what matters most to you. We also have information on other <u>medicines</u>, <u>surgery for Crohn's</u> or <u>surgery for Colitis</u> that you might find helpful.

How well does mirikizumab work in Ulcerative Colitis?

No medicine will work for everyone with Ulcerative Colitis. Currently, doctors do not know which medicine will work for a particular individual.

At first, the aim of mirikizumab treatment is to reduce the inflammation in your gut and get your Colitis under control. This is called induction treatment. Once your Colitis is under control, mirikizumab treatment aims to keep it under control. This is called maintenance treatment.

One large trial in 1,162 people looked at how well mirikizumab works as an induction and maintenance treatment for Colitis. The main outcomes were clinical remission and clinical response. Clinical remission is when there are few or no symptoms and little inflammation of the bowel. Clinical response is when there is some improvement, but the person is not in remission.

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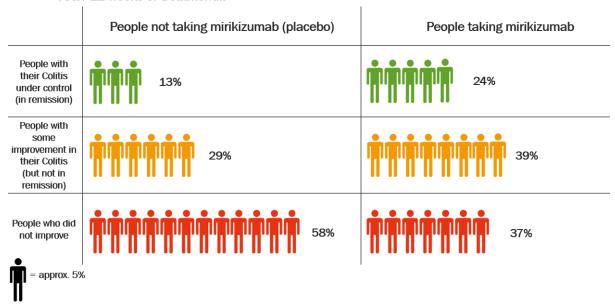
The trial also looked at any change in bowel urgency in people who had a high level of urgency at the start of the trial. Urgency is the sudden, intense feeling of needing to poo and having to rush to the toilet.

Getting Colitis under control with mirikizumab

The induction part of the trial compared mirikizumab, given by an infusion into the vein, with a placebo given in the same way. A placebo is a substance that looks the same as the treatment but does not have any medicine in it. Comparing mirikizumab to a placebo helps us see how effective it is.

After 12 weeks of treatment, 24 in every 100 people who had mirikizumab were in remission. Of the people who had placebo, 13 in every 100 were in remission.

After 12 weeks of treatment...



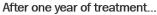


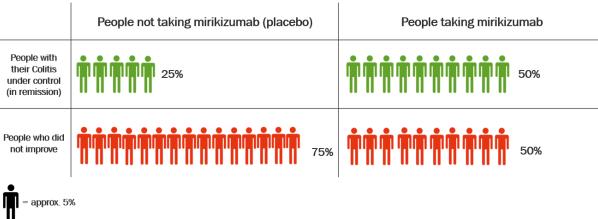


Keeping Colitis under control with mirikizumab

Of the people who had a clinical response after 12 weeks, 544 went on to the maintenance part of the trial. They either continued taking mirikizumab or switched to placebo. In this part of the trial, mirikizumab was given by an injection under the skin.

After 40 weeks of maintenance treatment, 50 in every 100 people who continued taking mirikizumab were in remission. Of the people who switched to placebo, 25 in every 100 were in remission.





There are no clinical trials that directly compare mirikizumab with other medicines that may be used at the same stage of treatment. But it is likely to have a similar effect to medicines such as ustekinumab and vedolizumab.

Effect of mirikizumab on urgency

Of the people who had reported having bowel urgency at the start of the trial, 43 in every 100 who took mirikizumab had no urgency or minimal urgency after one year. Of the people who switched to placebo, only 25 in every 100 had no urgency or minimal urgency.

Find out more about how we talk about the <u>effectiveness of medicines</u>.

How well does mirikizumab work in Crohn's Disease?





No medicine will work for everyone with Crohn's. Currently, doctors do not know which medicine will work for a particular individual.

At first, the aim of mirikizumab treatment is to reduce the inflammation in your gut and get your Crohn's under control. This is called induction treatment. Once your Crohn's is under control, mirikizumab treatment aims to keep it under control. This is called maintenance treatment.

Results from clinical trials

The information below shows the results of one large trial in 1065 people. This looked at how well mirikizumab works at getting people into remission.

How the trial was carried out

The researchers measured remission by:

- People saying they were in remission according to improvements in tummy pain and how often they had a poo. This was known as patient-reported outcomes.
- Endoscopy results.
- A scoring system, known as the Crohn's Disease Activity Index.

During this trial, researchers compared people who took mirikizumab with people who took a placebo. A placebo is a substance that looks the same as the treatment but does not have any medicine in it. Comparing mirikizumab to a placebo helps researchers see how effective it is.

Either mirikizumab or a placebo were given by an infusion into the vein at weeks 0, 4 and 8. They were then given as an injection under the skin every 4 weeks after that.

Study findings

Looking at patient-reported outcomes and endoscopy results

The study found that nearly 4 in every 10 people, or 38%, who were given mirikizumab said that they were in remission by week 12, and their endoscopy results at week 52 also showed they were in remission.

In comparison, nearly 1 in every 10 people, or 9%, who were given a placebo said that they were in remission by week 12, and their endoscopy results at week 52 also showed they were in remission.





People who said that they were in remission by week 12, and their endoscopy results at week 52 also showed they were in remission...

	People taking a placebo	People taking mirikizumab
People with their Crohn's under control, known as being in remission	9%	*** *** *** *** ***



Looking at patient-reported outcomes and Crohn's Disease activity index scores

The study found that nearly 5 in every 10 people, or 45%, who were given mirikizumab said that they were in remission by week 12, and their Crohn's Disease Activity Index score showed they were in remission at 52 weeks.

In comparison, nearly 2 in every 10 people, or 20%, who were given a placebo said that they were in remission by week 12, and their endoscopy results at week 52 also showed they were in remission.





People who said that they were in remission by week 12, and their Crohn's Disease activity index score at week 52 also showed they were in remission...

	People taking a placebo	People taking mirikizumab
People with their Crohn's under control, known as being in remission	20%	* * * * * * * * * *



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

How long does mirikizumab take to work?

Everyone responds differently to a new medicine. You might start to feel better as early as six weeks for Crohn's or three weeks for Colitis, after starting mirikizumab. But it may take longer and some people might not respond at all.

How to take mirikizumab

Dose of mirikizumab

You cannot take mirikizumab by mouth because it would be broken down by the gut, which stops it working. Instead, you are given it through a drip to start, and then as an injection under your skin.

You have your first three doses of mirikizumab through a drip into a vein. This is called an intravenous, or IV, infusion. You go to hospital to have this. You should have one infusion every four weeks for a total of three infusions.

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Mirikizumab Ed 1a





If you have had a good response to the first three infusions, you will switch over to having mirikizumab as an injection under your skin every four weeks. This is called a subcutaneous, or SC, injection. You might have this in hospital, or you may be able to give yourself the injection at home. See the section having the injection for more information.

If you have Colitis and you do not have a good response to the first three infusions, your IBD team may suggest that you continue having mirikizumab by infusion for another three doses. If you have a good response after these six infusions, you will switch over to having mirikizumab as an injection. If there is no improvement, your IBD team may suggest stopping mirikizumab and trying a different treatment.

For Crohn's, if mirikizumab stops working, your IBD team will help to decide the best way to treat you.

Having the infusion

You will have to go to hospital to have the infusion. You can often have it in a day unit, so you will only be there for a few hours. A doctor or nurse will give you the infusion through a drip into one of the veins in your arm.

- For Colitis, you will be given 300mg of mirikizumab over 30 minutes during each infusion.
- For Crohn's, you will be given 900mg of mirikizumab over 90 minutes during each infusion.

After this, the doctor or nurse will flush your drip through with a solution of saline. Saline is a mix of salt and water. This is to make sure that all the mirikizumab goes into your vein, and none is left in the drip. The flush should not be painful, but it may feel a bit cold.

After each of your infusions your doctor or nurse will probably keep an eye on you for up to one hour. This is to make sure that you are not having a reaction to the infusion. Mirikizumab is not likely to affect your ability to drive after your infusion.

Having the injection

Most people will be able to inject themselves with mirikizumab at home. But some people may continue to have their mirikizumab injection in hospital. If you are going to have it at home, you will need to learn how to inject yourself. Your IBD doctor, nurse or pharmacist, or someone from the home delivery team will teach you how to do this. If you





prefer, it may be possible for them to teach someone else to give you the injections. This might be a friend or family member.

Mirikizumab injections come ready to use in a pre-filled injection pen.

- For Colitis, the maintenance dose is 200mg every four weeks. To get this dose, you
 will need to have two injections, one right after the other. You need two injections
 because the amount of solution needed to make up the full dose is too much to
 inject under your skin in one go.
- For Crohn's, the maintenance dose is 300mg every four weeks. To get this dose, you will need to have two injections, one right after the other. You need two injections because the amount of solution needed to make up the full dose is too much to inject under your skin in one go. One injection will contain 100mg, and the other 200mg. These can be injected in either order.

For both Crohn's or Colitis, do not inject in the exact same spot every time. For example, if your first injection was in your tummy, your second injection could be in a different place in your tummy.

It is important to have both doses together, one immediately after the other. This is so that you have the best chance of mirikizumab working. If, for any reason, you cannot have the second dose straight away, contact your IBD team for advice.

Delivery

Your hospital may arrange for a special delivery company to send your mirikizumab injections to your home. Mirikizumab 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.

Storage

Keep mirikizumab injections in the fridge, between 2°C and 8°C. Keep them in the original carton to protect them from light. Do not microwave the pens, run hot water over them, or leave them in direct sunlight. Do not shake your pre-filled pen.

If needed, for example if you are travelling, you can keep mirikizumab injections out of the fridge for up to 14 days, or two weeks. You must keep them in the original carton at room temperature, up to 30°C. They must be out of direct sunlight. Do not use the injections if they are left out of the fridge for more than 14 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 to feel some pain, but these tips can help to make it easier to manage.

Let your medicine warm to room temperature

It might be uncomfortable if you inject yourself with mirikizumab straight from the fridge. Take it out of the fridge about 30 minutes before you inject it, so it can warm to room temperature. Do not warm the injection in any other way, such as in hot water or a microwave.

Apply an ice pack before you inject

You might find it helpful to apply an ice pack to the injection area for two to three minutes before you inject. If you do this, put a thin towel under it or wrap it in a cloth so it does not damage your skin.

Choose your injection site

The upper thigh or tummy, away from the belly button, are good places for the injection. Avoid any areas where the skin is red, scarred, bruised or hard. Do not use the same place every time.

Wash your hands and clean the skin at the injection site

Wash your hands with soap and water. Make sure the skin at the injection site is clean before you inject. You can use an alcohol wipe to do this. This is to reduce the risk of infection.

• Use a good injection technique

Place and hold the clear base of the pen flat and firmly against your skin, then unlock it. Listen for the first click; it means the injection has started. Keep pressing and holding the clear base firmly against the skin. When you hear the second click, it means that the injection is complete. Inject the second pen immediately after the first pen. Make sure the second injection is in a different place.

Use an ice pack after you inject

Some people recommend applying an ice pack or cold damp towel to the area for





10 to 15 minutes after you have injected to help with pain at the injection site. Remember to put a thin towel under the ice pack or wrap it in a cloth.

Wear loose clothing.
 Wear loose clothing to avoid rubbing or pressure on the injection site.

If you are having problems injecting your mirikizumab, ask your IBD team for help.

How long will you need to take mirikizumab for?

Your IBD team will review your treatment regularly to check whether it is still the best option for you. If it continues to work, then you will most likely continue treatment.

For Colitis, if mirikizumab stops working so well while you are on the injections, your doctor might decide to restart the infusions. This would mean having the infusion dose every four weeks for a total of three doses. If treatment starts working again, you will then resume the injections as before. If there is no improvement, your IBD team may suggest stopping mirikizumab and trying a different treatment.

For Crohn's, if mirikizumab stops working, your IBD team will help to decide the best way to treat you.

Stopping or changing treatment

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

- Mirikizumab is not working well. Your IBD team will give your medicine 24 weeks to work. They may stop treatment if it has not worked for you after this time or if you get worse during this time. This will depend on your condition and the practice at your hospital.
- You have side effects. You may need to stop taking mirikizumab if you have side effects that are:
 - o Serious
 - o Affecting your daily life
 - Hard to manage
- Mirikizumab becomes less effective. For Colitis, if mirikizumab stops working so
 well while you are on the injections, your doctor might decide to restart the
 infusions. This would mean having the infusion dose every four weeks for another





three doses. If treatment starts working again, you will then restart the injections as before. If there is no improvement, your IBD team may suggest stopping mirikizumab and trying a different treatment.

You have a right to take part in decisions about your treatment. Tell your IBD team what matters most to you. This will help them give you the information and support you need. Our <u>guide to appointments</u> can help you have these conversations. Do not stop taking your medicine unless your IBD team say it is ok. If you stop taking this medicine, but are still unwell, you may be able to try a different biologic or other targeted medicine. See our information on <u>biologics and other targeted medicines</u>.

Taking mirikizumab with other Crohn's or Colitis treatments

You may take mirikizumab on its own or with other medicines for your Crohn's or Colitis. Other medicines that you might take as well as mirikizumab include <u>5-ASAs</u>, <u>steroids</u> or an immunomodulator, such as <u>azathioprine</u> or <u>mercaptopurine</u>.

If you are taking steroids when you start mirikizumab, you might be able to stop them. Your IBD team will discuss this with you. It is important that you do not stop taking steroids without speaking to your IBD team.

Checks before starting mirikizumab

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

- You have an infection, or you are feeling unwell or feverish. You may need to delay
 your treatment if you have an infection. Also, let your IBD team know if you have
 often had infections in the past.
- You have ever had tuberculosis, also known as TB, or 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 mirikizumab. You will usually have a blood test or a chest X-ray to check for TB.
- You have HIV or hepatitis. Hepatitis is a liver infection caused by a virus. You will
 usually have a blood test to check for these viruses.





- You have ever had chickenpox, shingles, cold sores or genital herpes. If necessary, you may be able to be vaccinated against these before you start treatment.
- You have a condition or take any other medicine that weakens your immune system.

Your IBD team may also ask about any vaccinations you have had. This is to make sure that your vaccinations are up to date before you start mirikizumab. Let them know if you are going to have any vaccinations, or you have had a vaccination recently.

You will also have a blood test before you start treatment to check if your liver is working OK.

Tell your IBD team if you are pregnant, think you might be pregnant, or are planning to have a baby. They can discuss your treatment options with you. See the section on Pregnancy and fertility for more information.

Ongoing checks

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

You will have blood tests to check if your liver is working OK. This will likely be once a month for the first three months and then every one to four months throughout your treatment.

Special precautions

Mirikizumab affects the way your immune system works. So it might increase your risk of infection. Your immune system is still able to fight off infections, just not quite as well as other people's. You may find that infections affect you more than they used to. It may also take you longer to recover. Tell your IBD team if you have signs of an infection. This might include a sore throat, fever or any new symptoms that concern you. They may advise you to wait until you feel better before having mirikizumab. See the section on side effects.





Even though your risk of infection may be greater, it should not stop you from living life as before. See our information on <u>immunosuppressant precautions</u> to find out some practical things you can do to reduce your risk.

Side effects

All medicines can have side effects, but not everyone gets them. Some side effects can happen right away, others might happen later. Some side effects are mild and may go away on their own or after you stop taking mirikizumab. Others may be more serious and could need treatment. Some side effects might mean that mirikizumab is not right for you.

In clinical trials, the risk of getting side effects was similar in people taking mirikizumab to people not taking mirikizumab (the placebo group).

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

We also encourage you to report any side effects to the Medicines and Healthcare Products Regulatory Agency (MHRA). You can do this through the <u>Yellow Card scheme</u> <u>online</u> or by downloading the MHRA Yellow Card app (<u>yellowcard.mhra.gov.uk</u>). This helps collect important safety information about medicines.

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.

Infections

Because mirikizumab affects the way your immune system works, it can increase your risk of infection. The risk of getting a serious infection is probably similar to people who do not take mirikizumab. But, if you do get an infection, it may be more serious, and it may take you longer to recover. You may also be more likely to get an opportunistic infection. An opportunistic infection is an infection that happens more often or is more severe in someone with a weakened immune system. Opportunistic infections include shingles and thrush.

After starting the treatment, tell your GP or IBD team straight away if you have any signs of a serious infection such as:





- A high temperature, shortness of breath, a cough that will not go away or feeling more tired than usual. These may be signs of pneumonia.
- A high temperature, sweating, weight loss or a cough that will not go away. These
 may be signs of tuberculosis, also known as TB. Also, tell your doctor if you have
 recently been near anyone who might have TB.
- Needing to wee more often than usual, or a burning or stinging feeling when you
 wee. These may be signs of a urine infection.
- A painful skin rash with blisters. This may be a sign of shingles.

If you do get an infection, your IBD team might advise you to stop mirikizumab while the infection is treated. This will depend on where the infection is, and how bad it is. You will usually be able to start mirikizumab again when the infection is under control.

Allergic reactions

Up to 1 in every 100 people taking mirikizumab might have an allergic reaction to the infusion.

Contact NHS 111 straight away if you think you are having an allergic reaction. Signs to look out for include:

- Difficulty breathing or swallowing
- Feeling dizzy or light-headed
- Swelling of your face, lips, mouth or throat
- A rash or raised, itchy patches on your skin (hives)

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

Common side effects

These may affect up to 1 in every 10 people who take mirikizumab.

- Nose and throat infections
- Pain in your joints
- Headache
- Rash
- Redness and pain at the injection site





Uncommon side effects

These may affect up to 1 in every 100 people who take mirikizumab.

- Shingles. You may be able to have the shingles vaccine before you start treatment.
- A change in how your liver works. Your doctor may need to stop mirikizumab and do some more tests if this happens to you.
- Allergic reactions at the site of the infusion, such as an itch or skin rash. Serious allergic reactions are rare.

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/.

Taking other medicines

No studies have been done to check whether mirikizumab affects other medicines.

Speak to your doctor or pharmacist if you are taking, or plan to take, any other medicines. This includes medicines you buy from a pharmacy or supermarket, as well as herbal, complementary, or alternative medicines.

Vaccinations

If possible, make sure that you are up-to-date with your vaccinations before you start treatment with mirikizumab.

Live vaccines

- You should not have live vaccines until at least three months after your last dose of mirikizumab. But you may be advised to wait up to 12 months.
- If you have had a live vaccine, you should wait four weeks before starting mirikizumab.

Live vaccines are made using weakened versions of living viruses or bacteria. If you have a lowered immune system, there is a possibility they might cause infections. Live vaccines used in the UK include:

BCG for tuberculosis





- Chickenpox vaccine
- Measles, mumps and rubella vaccines either as individual vaccines or as the triple MMR vaccine
- Nasal flu vaccine used in children but the injected flu vaccine used in adults is **not** live
- Rotavirus vaccine babies only
- Yellow fever vaccine
- Oral typhoid vaccine but the injected typhoid vaccine is not live

There is a small risk that people who have received live vaccines 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: washing your hands after direct contact with the person who has had the vaccine, and before preparing food.

Non-live vaccines

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

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

People aged 18 years or older who are severely immunosuppressed also qualify for the shingles vaccine. This includes people taking a biologic, such as mirikizumab. A non-live shingles vaccine, Shingrix, is available.

Pregnancy and fertility

Fertility

We do not know if mirikizumab affects fertility.

The manufacturers of mirikizumab say that it should only be used in pregnancy if the benefit justifies any possible risk to mother or the baby. They recommend that people who could get pregnant should use effective contraception while taking mirikizumab. This is to prevent pregnancy. They recommend continuing to use contraception for at least 10 weeks (two to three months) after stopping mirikizumab.





Planning a pregnancy

Studies of mirikizumab in pregnant animals showed no evidence of harm to the unborn baby. But, there is very little information on its use in humans during pregnancy. Deciding whether to continue taking mirikizumab during pregnancy is a balance between keeping your Crohn's or Colitis under control and keeping any risk to your baby as low as possible.

Speak to your IBD team if you are offered or are taking mirikizumab and want to start a family. They can help you make an informed decision about your care and your baby's safety.

Do not stop taking your medicine without talking to your IBD team first.

Stopping your medicine may increase your risk of a flare-up. Having active Crohn's or Colitis can increase the risk of pregnancy complications, such as:

- Premature birth
- Low birth weight
- Miscarriage

This is why it is important to try to keep your condition under control during pregnancy.

If you have an unplanned pregnancy

Contact your IBD team straight away if you are on mirikizumab and find out that you are pregnant. Do not stop taking your medicine without speaking to your healthcare professional.

Your baby and live vaccines

It is important to tell your baby's healthcare team if you were taking mirikizumab during pregnancy or while breastfeeding. This is because your baby may have been exposed to the medicine. If you took mirikizumab during pregnancy, healthcare professionals may recommend delaying your baby's live vaccines until they are 6 to 12 months old.

Decisions on whether and when your baby should have live vaccines should be made on an individual basis. There might be times when it's OK for your baby to have a live vaccine. Sometimes the benefit of giving a live vaccine to your baby is greater than the potential risk. Speak to your IBD team. Yours and your baby's healthcare professionals should help you come to a decision.





See our information on <u>postnatal care and breastfeeding</u> for more on your baby's live vaccines.

We have separate information about reproductive health and pregnancy and birth.

Breastfeeding

There is no information on taking mirikizumab whilst breastfeeding.

The amount of mirikizumab in breastmilk is likely to be low. And any that is in the breastmilk is likely to be broken down in the baby's gut. So the amount that reaches the baby's blood stream is probably small. But until we have more information, experts advise that it should be used with caution in people who are breastfeeding.

Talk to your IBD team if you are taking mirikizumab and are planning to breastfeed. They can discuss your treatment options with you.

Drinking alcohol

At the moment, there is no information on whether it is safe to drink alcohol while you are taking mirikizumab.

Who to talk to if you are worried

<u>Taking medicines</u> 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 other options there might be. You should also get in touch with your IBD team if you have any new symptoms or side effects.

It can take time to find the medicine that's right for you. Don't be afraid to ask questions and seek out extra support when you need it.

This information is general and does not replace specific advice from your health professional. Talk to your GP or IBD team for information that's specific to you.





Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our award-winning information on Crohn's Disease, Ulcerative Colitis, and other forms of Inflammatory Bowel Disease have the information you need to help you manage your condition.

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

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

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 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 own 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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CROHN'S & COLITIS UK



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