



Risankizumab

This information is for people with Crohn's or Colitis who are on risankizumab (Skyrizi) treatment or who are thinking about starting it. Our information can help you decide if this treatment is right for you. It looks at:

- How the medicine works
- What you can expect from the treatment
- Possible side effects
- Stopping or changing treatment

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

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Key facts about risankizumab

- Risankizumab is used to treat Crohn's and Colitis. It can help get your symptoms under control and keep them under control. But it does not work for everyone.
- Risankizumab is free throughout the UK for people who are entitled to NHS care.
- You have your first three doses of risankizumab through a drip into a vein. You have one dose every 4 weeks.
- After this, you have it as an injection under your skin. You can learn to do this at home using a special on-body injector. You have one injection every 8 weeks.
- Risankizumab alters your immune system, so your body might not be able to fight off infections as well as it used to. Contact your IBD team straight away if you think you have an infection.
- If you could get pregnant, you are advised to use effective contraception while you are on risankizumab and for at least 21 weeks after you stop treatment.
- If you're taking risankizumab and you're pregnant or planning to get pregnant, talk to your IBD team. They can discuss your treatment options with you.
- You should not have live vaccines when you are taking risankizumab and for at least 21 weeks after you stop treatment.
- If you have any concerns about risankizumab treatment, contact your IBD team.

Other names for risankizumab

The brand name for risankizumab is Skyrizi.



How risankizumab works

Risankizumab is an antibody that's made from living cells in a lab. It is a type of [biologic medicine](#).

Antibodies are proteins that recognise and stick to specific targets. Risankizumab sticks to a target called IL-23. Your immune system naturally makes IL-23 to help you fight infections. But in people with Crohn's or Colitis, it can also cause inflammation.

Risankizumab blocks the effects of IL-23. This reduces gut inflammation. But, like many other treatments for Crohn's or Colitis, it also alters your immune system.

Why you might be offered risankizumab

Risankizumab can only be prescribed by a specialist in a hospital. It aims to get your condition under control and keep it under control.

If you have Colitis

Risankizumab is a treatment option for adults with moderately to severely active Ulcerative Colitis.

Your IBD team might suggest it for you if you have Colitis and:

- You cannot take an anti-TNF medicine such as [adalimumab](#), [infliximab](#) or [golimumab](#)
- You have not responded well enough to an anti-TNF medicine
- You have stopped responding to an anti-TNF medicine
- You have had to stop taking an anti-TNF medicine because of bad side effects

If you have Crohn's

Risankizumab is a treatment option for people over 16 with moderate to severely active Crohn's.



Your IBD team might suggest it for you if you have Crohn's and:

- You did not respond well enough to another biologic medicine or
- You stopped responding to another biologic medicine or
- You had to stop another biologic medicine because you had bad side effects or
- Biologic medicines called anti-TNFs ([adalimumab](#) or [infliximab](#)) are not suitable for you

Risankizumab is also used to treat a skin condition called psoriasis, and arthritis linked to psoriasis.

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 you might get
- Whether you need ongoing tests or checks
- Other medicines you're on

You could use our [Medicines Tool](#) to help you think about your options. Or our [appointment guide](#), which includes a list of questions you might want to ask. It can help you focus on what matters most to you. We also have full information on other [medicines](#) or [surgery](#) that you might find helpful.



How well does risankizumab work in Crohn's or Colitis?

Risankizumab can be effective at improving symptoms and keeping your condition under control. But it does not work for everyone. It is not possible for your doctor to predict which treatment will suit you best. Different medicines work for different people. It may take some time to find the right medicine for you. Find out more about [taking medicines](#).

Induction treatment and maintenance treatment

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

Some clinical trials look at how well a medicine works as induction treatment. Some look at how well it works as maintenance treatment. Some look at how well it works for both. We do not always have the same information for different medicines or different conditions. But we will include it when we do.

The people in the trials are given risankizumab or a placebo. A placebo is a substance that looks the same as the treatment but does not have any medicine in it.

Find out more about how we talk about the [effectiveness of medicines](#).







Getting Crohn's under control with risankizumab

These results come from two large clinical trials which compared risankizumab and placebo as induction treatment. Everybody in the trials had already been treated with Crohn's medicines that had not worked or had stopped working. Some of them had already been treated with biologic medicines. Some had not.

The table below shows how well the recommended dose of risankizumab got Crohn's under control after 12 weeks of treatment.



How well risankizumab got Crohn's under control

	People not taking risankizumab (placebo)	People taking risankizumab
People with their Crohn's completely under control (in remission)	 22%	 44%
People whose Crohn's improved but was not completely under control	 11%	 16%
People whose Crohn's did not improve much or at all	 67%	 40%

Icon key: each person represents around 5%

More people had their Crohn's under control after taking risankizumab compared to people taking placebo. Around 44 in every 100 people (44%) had their Crohn's under control after 12 weeks of risankizumab treatment. Around 22 in every 100 people (22%) taking placebo had their Crohn's under control after 12 weeks. But not everyone responded to risankizumab.

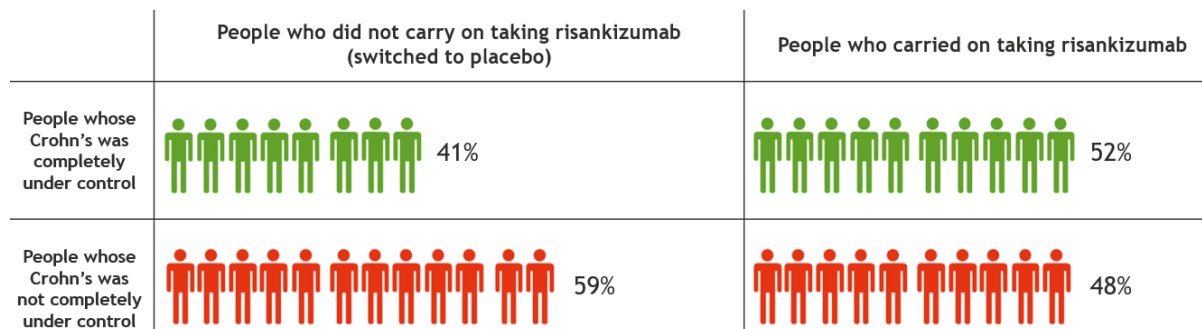
Keeping Crohn's under control with risankizumab

In clinical trials of risankizumab, people whose Crohn's improved after 12 weeks of treatment either carried on taking risankizumab or switched to placebo for maintenance treatment. It's important to know that not everyone in these trials had their Crohn's in remission at the start of maintenance treatment.

The table below shows how many people had their Crohn's completely under control after a year of maintenance treatment.



How well risankizumab kept Crohn's under control



Icon key: each person represents around 5%







More people had their Crohn's completely under control after taking risankizumab maintenance treatment than after taking placebo maintenance treatment. Around 52 in every 100 people (52%) still had their Crohn's under control after taking risankizumab for a year. This included people who had not responded to biologic medicines in the past. But not everyone carried on responding to risankizumab.

Getting Colitis under control with risankizumab

These results come from one large clinical trial of risankizumab induction treatment. The trials compared risankizumab to placebo in people with moderate to severely active Colitis. Everybody in the trials had already been treated with Colitis medicines that had not worked or had stopped working. Some of them had already been treated with biologic medicines. Some had not.



The table below shows how well the recommended dose of risankizumab got Colitis under control after 12 weeks of treatment.

	People not taking risankizumab (placebo)	People taking risankizumab
People with their Colitis completely under control (in remission)	 6%	 20%
People whose Colitis improved but was not completely under control	 30%	 44%
People whose Colitis did not improve much or at all	 64%	 36%

Icon key: each person represents around 5%

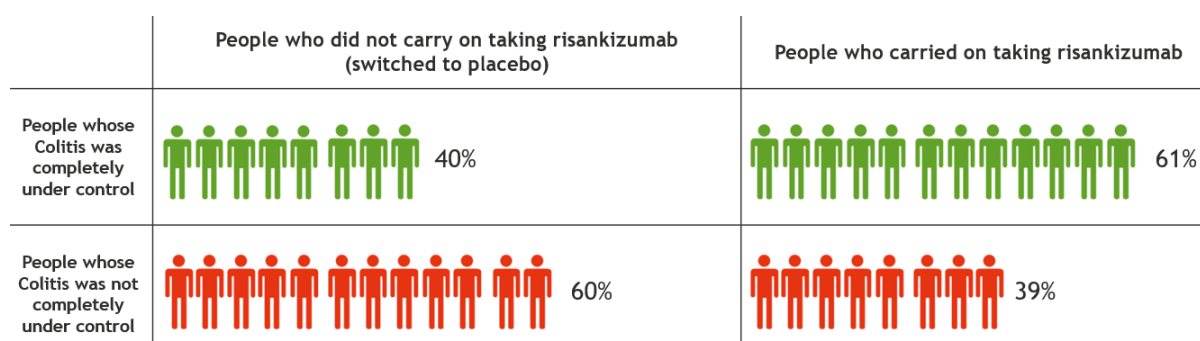
More people had their Colitis under control after taking risankizumab compared to people taking placebo. Around 20 in every 100 people (20%) had their Colitis under control after 12 weeks of risankizumab treatment. Around 6 in every 100 people (6%) taking placebo had their Colitis under control after 12 weeks. But not everyone responded to risankizumab.

Keeping Colitis under control with risankizumab

People who responded to 12 weeks of risankizumab treatment either carried on taking risankizumab or switched to placebo for maintenance treatment. For maintenance treatment, the trial looked at how well risankizumab kept Colitis under control after another 52 weeks of treatment.



The table below shows how well risankizumab **kept** Colitis completely under control in people whose Colitis was completely under control after induction treatment.



Icon key: each person represents around 5%

More people had their Colitis completely under control after taking risankizumab maintenance treatment than after taking placebo maintenance treatment. Around 61 in every 100 people (61%) still had their Colitis under control after taking risankizumab for a year. But not everyone carried on responding to risankizumab.

How does risankizumab compare to other medicines?

There have not been any clinical trials that compared risankizumab directly to other medicines for Crohn's or Colitis.

How long does risankizumab take to work?

Everyone responds differently to a new medicine. Most people who respond to risankizumab start feeling better within 4 to 12 weeks. In some people it could take longer. Some people might not respond at all.



How to take risankizumab

You cannot take risankizumab by mouth because it is broken down by the gut, which stops it working. Instead, you have it through an intravenous infusion (drip) for your first three doses, and then as an injection under your skin.

- You have your first three doses of risankizumab through a drip into a vein. This is called an intravenous infusion. You go to hospital to have it. It takes about 1 hour to have the infusion. You have one infusion every 4 weeks.
- After three infusions, you switch to having risankizumab as an injection under your skin. You have it through a special injector that you stick to your skin, called an on-body injector. Your doctor or nurse will teach you how to use it yourself at home. If you're not comfortable injecting yourself, tell them. They could teach a friend or family member to do it for you. Or they might be able to arrange for a nurse to give you your injection at home.
- You have your first injection 12 weeks after your first dose of risankizumab. This will be 4 weeks after your last infusion.
- After this, you have an injection every 8 weeks.





Taking risankizumab at home

Risankizumab comes in a box containing one cartridge of medicine and one on-body injector. The cartridge and injector are single-use only.



You must keep risankizumab in the fridge at a temperature of 2°C to 8°C. Do not freeze it. You can keep it out of the fridge for up to 24 hours, but at no more than 25°C. Keep it in its box to protect it from light.

Do not use any doses that are past their expiry date or have ever been frozen, even if they have thawed. Your pharmacist can tell you how to dispose of them.

Tips on injecting

Your doctor or nurse will teach you how to inject yourself with risankizumab. The Patient Information Leaflet also contains detailed instructions on what to do. This is in the box. It is sometimes called a Package Leaflet. You can also get it online: [Patient Information Leaflet for risankizumab injection](#).

Using the on-body injector might seem a bit daunting at first. But in clinical trials, over 9 in 10 people who used it said it was easy or very easy to use from the first dose.



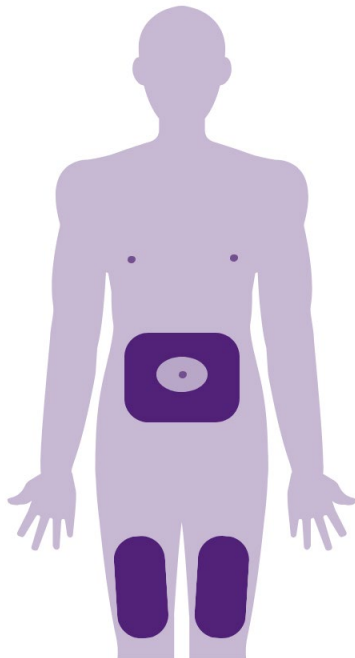
One of the common side effects of risankizumab is pain and redness at the injection site. These tips can help:

- **Allow your medicine to come up to room temperature**

It can be uncomfortable if you inject yourself with risankizumab straight from the fridge. Take it out of the fridge around 45 to 90 minutes before you inject it. Leave it in its box and let it come up to room temperature naturally. You should not warm it in any other way, such as in hot water, in a microwave or by rubbing or rolling it in your hands.

- **Choose your injection site**

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



- **Wash your injection site**

Make sure the skin is clean before you inject yourself. This is to help prevent infections.

- **Make sure the on-body injector sticks well**

Let your skin dry completely and choose a place where the on-body injector will



stick well. If you're injecting your tummy, pull your skin gently to create a firm, flat surface. Avoid skin folds and bulges. Do not move the on-body injector once you have stuck it on.

- **Try not to move around too much**

Once you've started the on-body injector, it takes around 5 minutes for the whole dose of medicine to go in. You can walk around, bend and reach but try not to be too active.

- **Check your skin afterwards**

When you remove the on-body injector, there might be a few drops of liquid on your skin and the injection site might bleed slightly. Press a cotton wool ball or pad over the injection site for about 10 seconds.

Dosage

If you have Crohn's

For your first three doses, you have 600mg of risankizumab every 4 weeks. These are the doses you have in hospital through a drip.

After this, all the rest of your doses are 360mg. This is one cartridge of medicine that you have through an on-body injector every 8 weeks. If you miss a dose, take it as soon as you remember.

If you have Colitis

For your first three doses, you have 1200mg of risankizumab every 4 weeks. These are the doses you have in hospital through a drip.

After this, all the rest of your doses will be either 180mg or 360mg. This is one cartridge of medicine that you have through an on-body injector every 8 weeks. If you miss a dose, take it as soon as you remember.



How long to take risankizumab

If you respond to risankizumab and have no serious side effects, you are likely to carry on taking it for at least a year. Every year, your IBD team should assess you to check whether continuing risankizumab is the best option. If you, or your IBD team, feel that it is no longer right for you, you should discuss other treatment options together.

Stopping or changing treatment

There are a few reasons why you or your IBD team might think about stopping or changing your treatment:

- **Your condition is under control**

Your IBD team will review how well you are responding to risankizumab at regular intervals during your maintenance treatment. If your condition stays under control for a prolonged period (usually a year or more), you might be able to stop taking risankizumab. If this is the case, your IBD team will discuss it with you and make the decision together. You can tell them if you have any concerns about stopping. If you stop risankizumab and you become unwell again, you should have the option to start risankizumab treatment again.

- **Risankizumab has not worked**

Your IBD team will review your response to risankizumab during the induction period. If your condition does not get better when you're taking risankizumab, they might suggest stopping risankizumab and trying a different treatment option.

- **Risankizumab stops working well**

Some people make antibodies that stick to risankizumab. It does not seem to stop risankizumab working, but it is possible that it could stop working over time. If this happens, your IBD team might suggest stopping risankizumab and trying another treatment.

- **You have side effects**

If you have side effects that are serious or hard to manage, stopping risankizumab might be the best option for you.



- **Difficulty injecting yourself**

If you are struggling with the injections, you might prefer to try a treatment you can take by mouth or have through a drip in hospital. Or you could ask your IBD team if they can arrange for a nurse to give you your injections at home, although this may not be possible.

Do not stop taking risankizumab without discussing it with your IBD team.

If risankizumab is no longer the best treatment for you, your IBD team should discuss other treatment options with you. You should consider the potential benefits, possible risks, and the goals of your treatment together.

Taking risankizumab with other treatments

In clinical trials, it was safe to take risankizumab alongside [steroids](#). The clinical trials did not look at whether it was safe to take it alongside other immunosuppressants or [biologic medicines](#). Your IBD team will talk to you about whether you need to take other medicines.

Do not stop steroid treatment without talking to your IBD team.



Checks before starting risankizumab

Having treatment that alters your immune system makes you more likely to get infections. And it may cause any inactive infections you have in your body to become active again. Before you start risankizumab, your IBD team will do thorough checks to make sure it's suitable for you. They may:

- Check if you've ever had chicken pox, shingles, TB (tuberculosis), cold sores or genital herpes
- Ask if you've ever travelled or lived in a place where TB is very common or if you live with anybody who's had TB
- Find out if all your vaccinations are up-to-date
- Take blood tests to check for TB, hepatitis viruses, the chicken pox or shingles virus, and HIV
- Do a chest X-ray to check for TB

If you have an infection, you might need to delay starting risankizumab until it's been treated.

You should not take risankizumab if you have active TB. If you have underlying, inactive TB, it needs to be treated before you start risankizumab.

You should wait 4 weeks after having any [live vaccines](#) before you can start risankizumab. You should not have any live vaccines until at least 21 weeks after your last dose of risankizumab.

Ongoing checks

After you start risankizumab, you should have regular checks to see how well it is working. Your IBD team will ask about your symptoms, any side effects you may be getting, and how you're managing with the injections. They will also check for any signs of infection. You might have blood tests and faecal calprotectin testing. Your IBD team will tell you what checks you need and how often.



Once you've got used to risankizumab, you should have a check-up every year. This is to check if you are still responding to risankizumab or whether you need to change the dose or stop treatment.

Special precautions

Risankizumab alters your immune system, so your body might not fight off infections as well as other people. You might get more infections than you used to. Or they might last longer or be more serious than usual.

Up to 1 in every 10 people taking risankizumab might get a cold, a cough or a throat or sinus infection. Up to 1 in every 100 people taking risankizumab might get skin infections.

Contact your GP or NHS 111 straight away if you think you have an infection

Signs to look out for include:

- Flu-like symptoms – a high temperature, feeling hot and cold, shivering or sweating
- A cough that will not go away
- Warm, red skin or a painful skin rash with blisters
- Feeling tired or short of breath

If you have an infection, you may need urgent treatment. Your IBD team might advise you to stop taking risankizumab until you are better.

To reduce your risk of getting an infection, try to avoid close contact with people who have infections. It's sensible to wash your hands often, especially before meals and after using the toilet. And take care to [store and prepare food safely](#).



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 risankizumab. Others may be more serious and could need treatment. Some side effects might mean that the risankizumab is not right for you.

In clinical trials, the risk of getting side effects was similar in people taking risankizumab to people taking placebo.

Speak to your IBD team if you get 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 [Yellow Card scheme online](#) or by downloading the MHRA Yellow Card app. 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.

Allergic reactions

Rarely, people taking risankizumab might have an allergic reaction. In clinical trials, this happened to less than 1 in every 100 people taking risankizumab.

Call 999 if you have difficulty breathing or swallowing



Contact NHS 111 straight away if you think you have any other signs of an allergic reaction

Signs to look out for include:

- 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.

Most common side effects

Here, we list the most common side effects of risankizumab. These might affect 1 to 10 in every 100 people taking risankizumab:

- Common cold, sore throat or sinus infections (this might affect more than 10 in every 100 people taking risankizumab)
- Headache
- Tiredness
- Itching
- Pain and redness where the injection went in
- Fungal skin infections
- Eczema – dry, itchy patches of skin

This is not a full list of side effects. There is information about less common side effects of risankizumab in the Patient Information Leaflet. This is also called a Package Leaflet. It should be in the box with your medicine. You can also get it online: [Patient Information Leaflet for risankizumab injection](#).



Taking other medicines

There is no evidence that risankizumab interacts with other medicines. But it's always best to check first.

Speak to your doctor or pharmacist if you're 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

- You should not have live vaccines until at least **21 weeks** after your last dose of risankizumab.
- If you have had a live vaccine, you should wait **4 weeks** before starting risankizumab.

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:

- TB vaccine
- Shingles vaccine – but a non-live version is also available and the live version is gradually being phased out
- Chickenpox vaccine
- Measles, mumps and rubella vaccines
- Nasal flu vaccine used in children – but the injected flu vaccine used in adults is **not** live
- Rotavirus vaccine
- Yellow fever vaccine
- Oral typhoid vaccine – but the injected typhoid vaccine is **not** live



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

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 [COVID-19 vaccination](#). These are **not** live vaccines.

We have not found any clinical trials that looked at the best time to have vaccinations in relation to your risankizumab dose.

Pregnancy and fertility

Risankizumab did not have harmful effects on pregnancy or fertility during studies on animals. But we do not know how it affects pregnancy or fertility in humans.

- If you could get pregnant, you are advised to use effective contraception while you are on risankizumab and for at least 21 weeks after you stop treatment.
- If you're taking risankizumab and you're pregnant or planning to get pregnant, talk to your IBD team. They can discuss your treatment options with you. Having Crohn's or Colitis that is not under control can itself lead to problems during pregnancy. So your team will discuss options to keep your condition under control and keep any potential risk to your baby as low as possible.

We have separate information about [Reproductive health](#) and [Pregnancy and breastfeeding](#).

Breastfeeding

We do not know if risankizumab passes into breastmilk.

In theory, it is likely to pass into breastmilk in very low levels. It is also likely to be destroyed in your baby's gut so most of it will not be absorbed into their bloodstream. But this has not been tested so we do not know for sure.



If you are thinking about breastfeeding while you're taking risankizumab, talk to your IBD team. They can help you weigh up the benefits of breastfeeding during treatment against the possible risks.

We have separate information about [Pregnancy and breastfeeding](#).

Drinking alcohol

There is no evidence that drinking alcohol affects the way your body deals with risankizumab. But to keep the health risks from alcohol low, it is best to keep to [recommended limits](#).

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 [helpline](#) 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.



About Crohn's & Colitis UK

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

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

About our information

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not intended to replace advice from your own doctor or other professional. We do not endorse any products mentioned.

We hope that you've found this information helpful. You can email the Knowledge and 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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