INTRODUCTION

This information is for anyone with Crohn’s or Colitis who is considering, or has started, treatment with adalimumab.

It looks at:

- how the drug works
- what you can expect from treatment
- possible side effects
- stopping or changing treatment.

The information also aims to help you talk to your IBD team about the possible benefits and risks of adalimumab. And ask all the questions you need to make an informed decision about your treatment.

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OTHER NAMES FOR THIS MEDICINE

Adalimumab is a biological medicine. It is known by the brand names Humira, Hulio, Imraldi, Hyrimoz, Amgevita.

Humira was the first version of adalimumab to be made and is the ‘originator’ medicine. Hulio, Imraldi, Hyrimoz, Amgevita are ‘biosimilars’ of Humira. They work in the same way and have same treatment effects but there will be some slight differences between them. For more information about biosimilars see Biologic Drugs.

You should be prescribed the drug by brand name so that it is clear which brand of adalimumab is being used.

WHY AM I BEING OFFERED TREATMENT WITH ADALIMUMAB?

The aim of treatment with adalimumab is to reduce inflammation in the gut, improve symptoms, maintain remission and provide better quality of life.

Adalimumab may be a suitable treatment when other drugs such as azathioprine or methotrexate (immunosuppressants) have not worked or have caused severe or hard to manage side effects. It can also be used if you have lost response to another biologic drug such as infliximab, or if surgery is not considered appropriate for you.

If you have Crohn’s Disease
Adalimumab is available to treat moderate to severe active Crohn’s Disease in adults, and moderate to severe active Crohn’s in children and young people from 6-17 years of age. It is used when treatment with other IBD medicines have not worked or when side effects have been severe.

If you have Ulcerative Colitis
Adalimumab is available to treat moderate to severe active Ulcerative Colitis in adults when treatment with other IBD medicines has not worked or when side effects have been severe.

HOW EFFECTIVE IS ADALIMUMAB?

Although not everyone responds to adalimumab, several large studies have shown that adalimumab can be effective in bringing about and maintaining remission in people with Crohn’s and Colitis.

The aim of treatment is to:
• reduce inflammation in the gut and bring about remission
• maintain remission (prevent flare-ups)
• improve quality of life by reducing or eliminating symptoms.

Crohn’s Disease
In large studies around 6 out of 10 people responded well to adalimumab initially. And of those more than 1 in 3 remained in remission after one year. It can also help to reduce the need for hospitalisation and surgery.
Adalimumab has been used to successfully treat fistulas in people with Crohn’s who also have active inflammation in their gut. A fistula is an abnormal channel, tunnel or passageway that connects one internal organ to another, or to the outside surface of the body. A fistula might connect two parts of the bowel to each other, or the bowel to the vagina, bladder or skin. Find out more in *Living with a Fistula*.

**Ulcerative Colitis**

In large studies over 5 out of 10 people with moderate to severe Ulcerative Colitis given adalimumab responded to treatment. And after one year around 1 in 4 remained in remission.

For some people with Crohn’s or Colitis adalimumab may be an effective option when treatment with another similar drug, infliximab, has not worked.

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**HOW DOES IT WORK?**

Adalimumab is a biological drug made from a synthetic (man-made) antibody. It works by targeting a protein in the body called tumour necrosis factor-alpha (TNF-alpha). Your body naturally produces TNF-alpha as part of its immune response, to help fight infections.

Over-production of this protein is thought to be partly responsible for the ongoing inflammation in the gut of people with Crohn’s or Colitis. Adalimumab binds to the TNF-alpha, this reduces the inflammation and helps to relieve symptoms. It is known as an anti-TNF drug.

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**HOW LONG WILL IT TAKE TO WORK?**

Everyone responds differently when taking a new medicine. You may begin to feel better within a few days, or it may take up to three months after you start treatment. However, adalimumab doesn’t work for everybody and it is important that you are followed-up by your IBD team to review how well it is working for you.

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**HOW DO I TAKE ADALIMUMAB?**

Adalimumab is given as an injection under the skin (subcutaneous injection). It cannot be taken by mouth in tablet form, because it would be destroyed by your digestive system.

Your adalimumab treatment will be supervised by a specialist doctor (gastroenterologist) experienced in the diagnosis and treatment of Crohn’s and Colitis. To begin with, a doctor or nurse will give you the injections. But once you are used to having the treatment, they will teach you how to inject yourself. Or you may be taught at home by a nurse from the company that supplies you with your medicine. 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.

**Adults**

Adalimumab for adult use comes ready to use in either a pre-filled syringe or a pre-filled injection ‘pen’. The syringes or pens come in a pack, which also contain an alcohol pad for cleaning the skin before injecting.
Children
Adalimumab for children may either come in a vial (small bottle) designed to fit onto a syringe using an adapter, a pre-filled syringe or pre-filled pen.

Delivery
Usually, adalimumab will be delivered directly to your home by a special home delivery company.

Storage
The drug must always be kept in the fridge, or it will not work. If you are travelling, adalimumab can be stored at room temperature (25°C) out of sunlight for a maximum of 14 days. But it must be used within the 14 days or thrown away, even if it has been put back in the fridge. A small cool bag can be useful to carry your medication - find out more about travelling with adalimumab in Travel and IBD.

TIPS ON INJECTING ADALIMUMAB

One of the most common side effects of adalimumab injections is pain at the injection site, sometimes with redness, itching and swelling. These tips can help:

• Allow your medication to warm to room temperature
  If you inject yourself with cold adalimumab straight from the fridge it may be uncomfortable. Try taking it out of the fridge around 15-30 minutes before you take it so it can warm to room temperature. You must not leave adalimumab out of the fridge for more than 30 minutes. If you think you have left it out of the fridge longer than this, do not use it, put it back in the fridge and contact your IBD team as soon as possible.

• Apply an ice pack before you inject
  If you are worried about pain at the injection site you could try applying an ice pack to the area for 2-3 minutes before you inject.

• Clean with an alcohol wipe
  Remember to clean the skin with an alcohol wipe before you inject yourself.

• Choose your injection site
  The upper thigh or stomach (away from the belly button) are good places for the injection – but avoid any areas where the skin is red, scarred, bruised or hard.

• Use a good injection technique
  Use a quick, dart-like motion to insert the needle into the pinched skin. Push the plunger slowly and evenly to inject all of the medicine, keeping pressure on the plunger head and keeping the skin pinched. If you use a syringe the injection will take about 2-5 seconds, if you use a pen this will take about 10 seconds.

• Apply an ice pack after you inject
  If your skin at the injection site hurts 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.

If you continue to have problems with pain at the injection site, you can ask your IBD team if you can try a different formulation of adalimumab.
WHAT IS THE NORMAL DOSAGE?

The dose you are prescribed and how often you need to take it will vary according to your condition. Children will be given smaller doses than adults. The starting dose if you have Crohn’s Disease may be different than that if you have Ulcerative Colitis.

**Crohn’s Disease**
Treatment starts with induction doses at week 0 and then week 2, which are higher to allow rapid response. These can either be 160mg and then 80mg two weeks later or 80mg and then 40mg two weeks later. The standard maintenance dose is 40mg every two weeks.

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If response to 40mg of adalimumab every other week reduces over time this may be increased to 40mg every week or 80mg every other week.

**Ulcerative Colitis**
Treatment starts with induction doses at week 0 and then week 2, which are higher to allow rapid response. This is 160mg and then 80mg two weeks later. The standard maintenance dose is then 40mg every two weeks.

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Your ongoing dose may be increased to 40mg every week, or 80mg every other week depending on how you respond to the treatment. The levels of the drug in your blood may also be measured by your team and these may also be used to help decide your dosing regimen.

Some types of adalimumab pre-filled pen or syringe contain 40mg of the drug. This means that you will need more than one injection when you have the initial doses.
HOW LONG WILL I BE TAKING IT?

You are likely to have a planned course of adalimumab lasting up to a year if symptoms improve and there are no serious unwanted effects. Treatment will be reassessed at least every 12 months to check if ongoing treatment is still right for you.

STOPPING OR CHANGING TREATMENT

There are a few reasons why you and your IBD team might think the time is right to stop or change your treatment.

Adalimumab is not effective – if there has not been any response to treatment within 12 weeks if you have Crohn’s or 8 weeks if you have Colitis. You may be able to try a different biologic drug such as infliximab, golimumab, vedolizumab or ustekinumab. See individual drug information sheets.

Stable remission - if at the end of the year your condition is in stable remission it may be decided that you can stop taking adalimumab. If you relapse after treatment has stopped, you should be able to start treatment again.

Side effects - treatment may be stopped if you experience side effects that are serious or difficult to manage.

Adalimumab becomes less effective - some people develop antibodies to adalimumab over time. This happens when the body produces an immune response to the drug. These antidrug antibodies may reduce the effectiveness of the treatment. If you have lost response to adalimumab and still have ongoing inflammation you may be able to switch to another biologic drug such as infliximab, golimumab, vedolizumab or ustekinumab. See individual drug information sheets and Biologic Drugs.

CAN ADALIMUMAB BE USED IN COMBINATION WITH OTHER DRUGS TO TREAT CROHN’S OR COLITIS?

Adalimumab is sometimes given with steroids to help bring on remission, after which steroid treatment can be reduced. It can also be used in combination with immunosuppressant drugs such as azathioprine or methotrexate.

There is some evidence that this combination therapy reduces the risk of developing antibodies to the drug. However, studies have suggested that combination therapies may also increase the risk of side effects, including infections and some types of cancer.

DO I NEED ANY CHECKS BEFORE I START TREATMENT?

Screening before treatment is essential to check that adalimumab is right for you. Make sure your IBD team know if you have a history of:

- Tuberculosis. If you have any history of tuberculosis (TB) or any recent exposure to people with TB. You should not be given adalimumab if you have active TB, and if you have underlying, inactive TB, this will need to be treated before starting adalimumab. Most doctors now use a blood test to check for underlying or inactive TB, but you may be given a chest x-ray as well.
• **HIV, hepatitis B or C.** If you have or have ever had any of these infections, are a carrier of hepatitis B or C (a viral liver infection), or have been in close contact with someone who has hepatitis B or C. You will usually have a blood test to check for these diseases before starting adalimumab.

• **Infections.** If you have a history of infections or currently have an infection (such as tonsillitis or a urinary tract infection) or have symptoms such as feeling feverish or generally unwell. If you have an infection your adalimumab treatment may need to be postponed until the infection has cleared. This is because taking adalimumab could make the infection worse. Stomach (away from the belly button) are good places for the injection – but avoid any areas where the skin is red, scarred, bruised or hard.

• **Heart problems.** If you have heart problems, adalimumab may make your symptoms worse, and your heart will need to be monitored closely before, during, and after treatment.

• **Cancer.** If you have a history of cancer. Adalimumab affects the way in which your immune system works, and you may have an increased risk of developing some types of cancer. However, you may also be at risk even if you do not have a history of cancer.

And tell your IBD team if:

• you smoke or have COPD (Chronic Obstructive Pulmonary Disease)

• you have ever had a disease that affects the nervous system, including any symptoms of numbness, tingling or vision problems such as multiple sclerosis.

• you have had kidney or liver disease.

• you are pregnant, planning to get pregnant or are breastfeeding.

• you are taking any other medications or have had any vaccinations recently.

• you are having any surgery.

• you travel to regions of the world where TB or fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis are common.

• 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 adalimumab.

**WILL I NEED ONGOING CHECKS?**

Once your treatment has started you will need regular checks, including blood tests. Monitoring your treatment helps your IBD team fit your treatment to your needs. It can also make sure that any problems with treatment are avoided or caught at an early stage.

At some hospitals, a blood test may also be used to check the levels of adalimumab in your blood. Blood tests can also help your IBD team see whether you have developed antibodies to it.
ADALIMUMAB

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

Because adalimumab affects the way your immune system works, you may be more prone to infections. Even a mild infection such as a cold or sore throat could develop into a more serious illness. Tell your doctor or hospital if you begin to feel unwell and think you might have an infection.

To reduce this risk:

- **Have the annual flu vaccination.** You will also be advised to have a pneumonia vaccination while on adalimumab treatment. Pneumococcal infections can lead to pneumonia (inflammation of tissue in the lungs), septicaemia (a kind of blood poisoning) and meningitis (an infection of the protective membranes that surround the brain and spinal cord).

- **Try to avoid close contact with people who have infections.** This includes viruses and bacteria that cause chickenpox and shingles, measles, and pneumococcal disease. Contact your doctor or the hospital if you begin to feel unwell and think you may have caught an infection.

- **Take care with food hygiene.** You may be more at risk of infections caused by bacteria found in food such as listeria. Avoid eating raw eggs or undercooked pate, meat and poultry, as well as unpasteurized dairy products which may include some soft or blue cheeses.

- **Take care in the sun.** Adalimumab can increase the risk of skin reactions, and in rare cases skin cancer. As do azathioprine and mercaptopurine, which may be prescribed alongside adalimumab. You should take extra precautions when in the sunlight, for example wearing a hat and high factor sun cream.

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF ADALIMUMAB?

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

Some adalimumab 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 adalimumab is not suitable for you.

IMMEDIATE REACTIONS

- **Reactions to the injection** such as pain or swelling, redness, bruising and itching. Using the adalimumab at room temperature or cooling your skin with an ice pack may help - see more in Tips on injecting adalimumab. Your doctor or IBD nurse should also be able to help you find ways to reduce this sort of reaction or you may be able to try a different brand of adalimumab.
• **Allergic reactions to adalimumab.** 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:**

• **Risk of infection** A greater chance of getting infections such as colds and flu and some more serious ones such as pneumonia and sepsis (general inflammation and problems with blood clotting). You may also be at greater risk of developing tuberculosis (TB) or of having underlying TB reactivated while on adalimumab. Symptoms of an infection often include feeling very tired, fever, cough, and warm painful skin. You may need to stop the adalimumab if you have an infection, so check with your medical team first if you think you have or are developing an infection.

• **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, sore throat, or looking very pale.

• **Liver problems.** Contact your doctor if your skin or eyes look yellow, you feel very tired with a lack of appetite, or you have a persistent pain on the right hand side of your tummy (abdomen). Adalimumab can also activate viral hepatitis if you carry it in your blood. Your doctor will check if you are a carrier before you start treatment, and continue with blood tests while you are on the drug to make sure it does not activate.

• **Skin reactions.** These include psoriasis (scaly patches) and eczema, other skin rashes and ulcers. Some of these can be treated without stopping

• **Some types of skin cancer.** You must tell your doctor if you have a bump or open sore which is not healing.

• **Cancers including lymphoma** (cancer of the lymph glands). This has been reported as an uncommon side effect of adalimumab (in around 1 in 1,000 people) and more rarely still, leukaemia (in around 1 in 10,000). You may be more at risk if you are also taking immunosuppressive drugs such as azathioprine or methotrexate. However, it is difficult to know what the exact risk is, as cancers in these circumstances happen rarely and very few people are affected.

• **Heart problems.** This includes heart failure or worsening of heart failure you already have. Call your doctor immediately if you get new or worsening symptoms of heart failure while taking adalimumab. This includes shortness of breath, swelling of your ankles or feet, or sudden weight gain

• **Damage to nerves.** This is a very rare complication that includes demyelination (damage to nerves) and some rare inflammatory conditions, including lupus (an autoimmune condition).

Many of these serious side effects are reversible if the drug is stopped.
TELL YOUR DOCTOR IMMEDIATELY IF YOU DEVELOP ANY OF THE FOLLOWING SYMPTOMS:

- A severe rash, hives (swollen red patches of skin) or other signs of allergic reaction
- Swollen face, hands and feet
- Trouble breathing or swallowing
- Shortness of breath

CAN I HAVE IMMUNISATIONS WHILE ON ADALIMUMAB?

It is unsafe to have “live” vaccines while on adalimumab and for five months after you stop treatment. Live vaccines contain viruses that have been weakened, but not destroyed. People who are taking medicines which affect the immune system may not be able to produce antibodies quickly enough and risk becoming infected by the disease.

Live vaccines include: 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 currently safe as the adult vaccines are not live. The Department of Health recommends that everyone on drugs such as adalimumab should have an annual flu vaccination. But if anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions.

If you have a baby whilst on treatment, your baby should not be given live vaccinations for five months after your last adalimumab injection during pregnancy.

IS IT SAFE TO TAKE OTHER MEDICINES ALONG WITH ADALIMUMAB?

Adalimumab may interact with other drugs.

Do not take medicines that contain the active substances anakinra or abatacept. These drugs are commonly used for treating Rheumatoid Arthritis.

Tell your doctor if you are taking or intend to take any over the counter medicines that you buy yourself. Or any herbal, complementary, or alternative medicines or therapies.

Do I need to tell other health professionals?
Tell any other doctor, dentist or other health professional treating you that you that you are taking adalimumab. Always carry the alert card while you are on the medication and for five months after your last treatment. This is provided by the company that makes the medicine.

DOES ADALIMUMAB AFFECT PREGNANCY?

Research is still ongoing into the possibility of long-term effects of adalimumab on the baby, and manufacturers state that adalimumab should only be used during pregnancy if clearly needed. They also advise using effective contraception to prevent pregnancy when you are taking adalimumab, and to continue using it for at least five months after your last treatment.
Your doctor should discuss the risks and benefits of taking adalimumab while pregnant and you may find it helpful to talk through your options with your IBD team. According to a review of pregnancy studies, there was no higher risk of birth defects when the mother received adalimumab during pregnancy, compared with mothers who did not receive adalimumab.

There is some evidence to show adalimumab is low risk during conception and for at least the first six months of pregnancy (first two trimesters). Stopping the medication from three to six months of pregnancy (second trimester) reduces the unborn baby’s exposure to the medication, but your doctor may consider it advisable to continue the drug in the last three months (third trimester), to keep your Crohn’s or Colitis in remission. This will reduce any risk associated with a flare up for both you and your baby.

If you take adalimumab while you are pregnant, your baby may have a higher risk of getting an infection. Before your baby receives any vaccine, it is important to tell your baby’s doctors that you received adalimumab while pregnant. Your baby should not be given live vaccinations such as BCG for six months after your last adalimumab injection during pregnancy.

There is less evidence for men wanting to father a child while on adalimumab, but it is thought that it is safe for a man to conceive a child while taking the drug.

If you are planning a pregnancy talk to your IBD team, and find out more in Pregnancy and IBD and Reproductive Health and IBD.

WHAT ABOUT BREASTFEEDING?

Adalimumab is present in breast milk in very small amounts. Because it is destroyed by the digestive system when taken orally, the adalimumab is likely to become ineffective and the manufacturer states that adalimumab can be used during breastfeeding.

Research is continuing into the possible effects small amounts of the drug might have on the baby, especially in the longer term. One study found breastfed infants of mothers on biologic drugs (such as adalimumab), immunosuppressants (such as azathioprine), or combination or the two therapies had similar risks of infection and rates of milestone achievement compared with non-breastfed babies. The study found that if you are taking a biologic drug you should still be able to breastfeed your baby. If you are worried talk to your IBD team.

CAN I DRINK ALCOHOL WHILE TAKING ADALIMUMAB?

Alcohol is not known to have any interaction with adalimumab. But for general health reasons it is best to keep within the UK Chief Medical Officers’ guideline limits of no more than 14 units of alcohol a week on a regular basis.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about your adalimumab treatment or have any questions, talk to your IBD team. They should be able to help you with any 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. You can also talk to the Crohn’s & Colitis UK Helpline.
This information is about adalimumab in general and is not intended to replace specific advice from your doctor or any other health professional. For further information, talk to your doctor or specialist IBD team. You can also look at the Patient Information Leaflet (PIL) supplied with your medication or go to www.medicines.org.uk/emc/.

HELP AND SUPPORT FROM CROHN’S & COLITIS UK

We offer more than 50 publications on many aspects of Crohn’s Disease, Ulcerative Colitis and other forms of Inflammatory Bowel Disease. You may be interested in our comprehensive booklets on each disease, as well as our other booklets and information sheets covering a variety of topics particularly:

- Biologic drugs
- Infliximab, Golimumab, Vedolizumab, Ustekinumab
- Living with a Fistula
- Pregnancy and IBD
- Reproductive Health and IBD
- Travel and IBD

All publications are available to download from crohnsandcolitis.org.uk/quick-list. Health professionals can order booklets in bulk by using our online ordering system.

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 Crohn’s or Colitis. 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 personal experience of IBD.

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 IBD. You can share your experiences and receive support from others at: facebook.com/groups/CCUKforum

Crohn’s & 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. Visit crohnsandcolitis.org.uk/local-network to find your nearest network.

Help with toilet access
If you become a member of Crohn’s & Colitis UK, you will get benefits including a Can’t Wait Card and a RADAR key. This card shows that you have a medical condition, and combined with the RADAR key will help when you need urgent access to the toilet when you are out and about. See our website for further information: crohnsandcolitis.org.uk/membership or call the membership team on 01727 734465.
Crohn’s & Colitis UK publications are research-based and produced in consultation with patients, medical advisers and other health or associated professionals. They are prepared as general information on a subject and are not intended to replace specific advice from your own doctor or any other professional. Crohn’s and Colitis UK does not endorse or recommend any products mentioned.

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We hope that you have found this leaflet helpful and relevant. If you would like more information about the sources of evidence on which it is based, or details of any conflicts of interest, or if you have any comments or suggestions for improvements, please email the Publications Team at publications@crohnsandcolitis.org.uk. 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.

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 publication 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.