



INFORMATION SHEET

USTEKINUMAB

INTRODUCTION

This information is for you if you're considering or have been prescribed treatment with ustekinumab (Stelera) for Crohn's Disease or Ulcerative Colitis. It looks at:

- what you can expect from treatment
- how the medicine works
- possible side effects

Our information can support you to make an informed decision about treatment that is right for you.

OTHER NAMES FOR THIS MEDICINE

Ustekinumab is also known by the brand name Stelara.

WHY AM I BEING TREATED WITH USTEKINUMAB?

Ustekinumab is used to treat moderate to severe active Crohn's Disease and moderate to severely active Ulcerative Colitis in adults. It can be an option when other treatments including steroids, immunosuppressants (such as azathioprine, mercaptopurine, methotrexate) or biologic medicines such as anti-TNF's infliximab, adalimumab or golimumab haven't been effective. Or if other treatments have stopped working or you've experienced side effects that are difficult to manage.

“

Ustekinumab returned me to remission from my worst flare yet. I was able to go back to work within a month, and gradually return to living a 'normal' life.

”

Claire, age 35, diagnosed with Crohn's Disease in 2003

HOW DOES IT WORK?

Ustekinumab belongs to a group of medicines called 'biological drugs'. Biological drugs are produced by a biological, rather than chemical, process. Ustekinumab is a synthetic (man-made) antibody that is created inside living cells.

Ustekinumab is an anti-Interleukin biological drug. It targets two proteins in the body called interleukin-12 (IL-12) and interleukin-23 (IL-23). IL-12 and IL-23 are naturally produced in the body to help fight infections by temporarily causing inflammation. IL-12 and IL-23 are increased in IBD and contribute to the ongoing, or chronic, inflammation in the digestive system.

Ustekinumab binds to both IL-12 and IL-23 which prevents them from working, helping to relieve inflammation and symptoms. Ustekinumab is known as an 'immunosuppressant' because it dampens down the activity of the immune system.

HOW LONG WILL IT TAKE TO WORK?

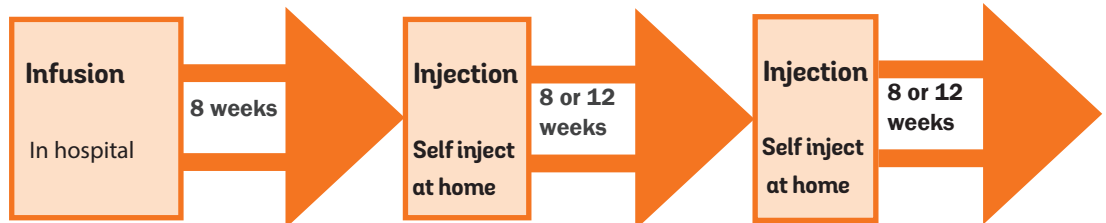
Everyone responds differently when taking a new medicine, and ustekinumab doesn't work for everyone. You may feel better as early as three weeks after taking ustekinumab, but most people who respond to ustekinumab start feeling better within six weeks. In some people it could take longer.

HOW LONG WILL I BE TAKING USTEKINUMAB ?

If you respond to ustekinumab and have no serious side effects, you may be put onto a planned course of treatment lasting up to a year, after which it may be extended. Your treatment plan will need to be reassessed at least every 12 months to check whether ongoing treatment with ustekinumab is right for you. If you are in stable remission, it may be decided that you can stop taking ustekinumab. But if after stopping treatment you become unwell again, you should have the option to restart. You may be taken off ustekinumab if you have any serious side effects or if you have not responded well enough within 16 weeks of starting your treatment.

HOW AND WHEN DO I TAKE USTEKINUMAB?

The first dose of ustekinumab is given in hospital as a drip into a vein in your arm - an intravenous (IV) infusion. The next dose is given as an injection under the skin - a subcutaneous injection 8 weeks later. You will then have further injections every 8 or 12 weeks. Your doctor will decide whether you will need to take ustekinumab every 8 weeks or every 12 weeks.



Ustekinumab comes in a pre-filled syringe containing 90mg. It can't be taken by mouth (in tablet form) because your digestive system would destroy it.

To begin with, a doctor or nurse will give you the injections. Once you are used to having the treatment, they will teach you the injection technique so that you can self-inject. If you prefer, it may be possible to train a family member or friend to give the injections.

Ustekinumab will be delivered directly to your home by a home delivery service at a time convenient to you. Ustekinumab should be kept in the fridge between 2-8°C and should not be frozen. If needed, it can be kept at room temperature, up to 30°C, for up to 30 days in the original box. Once ustekinumab has been stored at room temperature, it should not be returned to the fridge. Syringes should be discarded when they reach the expiry date, or after 30 days if left outside the fridge.

If you are unable to self-inject, the home delivery service can also provide a nurse to visit you at home to administer your injections. Ask your doctor about this service.

TIPS ON INJECTING USTEKINUMAB

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

- **Allow your medication to warm to room temperature**
If you inject yourself with cold ustekinumab 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. If needed, it can be kept at room temperature, up to 30 °C, for up to 30 days in the original box. Once ustekinumab has been stored at room temperature, it should not be returned to the fridge.
- **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.
- **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.

WHAT IS THE NORMAL DOSAGE?

The first dose of ustekinumab is approximately 6mg for every kg you weigh given as a drip into a vein in your arm, an intravenous (IV) infusion.

All following doses are 90mg regardless of what your weight is, and these are all given as an injection under the skin (subcutaneously).

HOW EFFECTIVE IS USTEKINIMAB?

Ustekinumab can be effective in improving symptoms and in bringing about and maintaining remission in people with moderate to severe Crohn's Disease and moderate to severely active Ucerative Colitis. This means that the inflammation in your gut is effectively reduced and your symptoms go away or significantly improve. Taking ustekinumab may also mean you no longer have to take steroids.

Some smaller studies suggest ustekinumab may also be effective in treating perianal fistulating Crohn's Disease. A perianal fistula connects the anal canal (back passage) to the surface of the skin near the anus. You can find out more in our information sheet **Living With a Fistula**.

WILL I NEED ANY CHECKS BEFORE TAKING USTEKINUMAB?

Before you start treatment, it is important to make sure that ustekinumab is right for you. Make sure the team treating you know:

- if you have ever had an allergic reaction to ustekinumab or latex (the needle cover of the pre-filled syringe contains latex), or if you are allergic to any of the other ingredients. The ingredients can be found in the Patient Information Leaflet that comes with your medicine, or can be downloaded from **www.medicines.org.uk**.
- if you have any history of tuberculosis (TB) or any exposure to people with TB. You should not be given ustekinumab if you have active TB. If you have underlying, inactive TB, this will need to be treated before starting ustekinumab.
- if you have a history of infections, currently have an infection or have symptoms such as feeling feverish or generally unwell. If you have an infection your treatment with ustekinumab may need to be postponed.
- if you have a history of cancer. Ustekinumab may slightly increase the risk of developing some types of cancer, such as skin cancer. This hasn't been seen in studies of people taking ustekinumab for Crohn's, but may be possible because of how ustekinumab affects the immune system. You may also be at risk even if you do not have a history of cancer.
- if you are having or have ever had injections to treat allergies. It is not known if ustekinumab affects these.
- if you are pregnant, planning to get pregnant, or are breastfeeding.
- if you are taking or have recently taken any other medicines, including other biological drugs such as adalimumab or infliximab or immunosuppressive drugs such as azathioprine, mercaptopurine or methotrexate.
- if you have recently had or will have any vaccinations.

WILL I NEED ONGOING CHECKS?

Once your treatment has started you will need regular checks to see whether ustekinumab is working for you. This will also help your doctors prevent any potential complications or catch them at an early stage. Ustekinumab weakens your immune system, so you will also be monitored for signs of infection. Your IBD team will tell you what checks you need and how often. It is important that you tell your doctor or the hospital team monitoring your treatment about any new symptoms you notice, as soon as they occur.

After 12 months of treatment, your IBD team should give you a check-up to see whether you should continue having ustekinumab.

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF TAKING USTEKINUMAB?

Like all drugs, ustekinumab can have side effects, although not everyone experiences these. Some side effects can happen almost immediately, others may not appear for several days, weeks or even longer. Some side effects are likely to be quite mild and may go away on their own. Others can be more serious and may require treatment, or may mean that ustekinumab is not suitable for you.

Side effects of ustekinumab include the following:

IMMEDIATE REACTIONS

It is not common, but some symptoms may mean you are having an allergic reaction to ustekinumab. Contact your IBD team immediately if you notice any of the following symptoms right after you take ustekinumab, or in the days following an infusion or injection.

- difficulty breathing or swallowing
- swelling in any part of the body
- dizziness or light-headedness
- redness of the skin, an itchy rash or itchy skin.
- pain in the part of your arm where the infusion needle was inserted
- chills, shivering, or high fever

OTHER SIDE EFFECTS

Ustekinumab weakens the immune system and may make you more likely to get infections. Tell your doctor straight away if you notice any of the following symptoms that may be a sign of infection:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- a cough that won't go away
- superficial fungal infections
- warm, red, painful skin, or a painful skin rash with blisters
- burning when passing urine

Common side effects that may affect up to 1 in every 10 people taking ustekinumab include:

- sore throat or common cold
- dizziness or headaches
- diarrhoea, nausea or vomiting
- itching
- back pain, muscle pain, joint pain
- fatigue or feeling tired

Less commonly, some people taking ustekinumab may develop tooth infections, a blocked nose, depression, bleeding or bruising at the injection site, temporary sagging of the muscles on one side of the face, or women may develop vaginal infections.

Although rare, and not reported for people with Crohn's, those with psoriasis may develop serious skin conditions called erythrodermic psoriasis or exfoliative dermatitis. Tell your doctor immediately if you notice an increase in redness or shedding of skin over a large area.

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Having ustekinumab on a much more spread out basis (8-12 weeks) means I don't have the experience of side effects every week after the injection like I did with my previous biologic.

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Ally, age 21, diagnosed with Crohn's Disease in 2015

It is best to let your doctor or IBD team know about any new symptoms you develop while taking ustekinumab, whenever they occur. They will be able to help you with any queries or concerns.

This is not a complete list of side effects for ustekinumab. For more information see the Patient Information Leaflet provided with your medication, or visit www.medicines.org.uk.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE TAKING USTEKINUMAB?

You will need to look out for any of the symptoms listed in the side effects section. Tell your IBD team immediately if you think you are having an allergic reaction.

Ustekinumab affects your immune system, so try to avoid close contact with people who have infections. Contact your doctor if you begin to feel unwell and think you may have caught an infection. It is recommended that you have an annual flu jab.

As ustekinumab is a drug that weakens the immune system, it may theoretically increase your risk of developing some cancers. This hasn't been seen in studies of people with Crohn's taking ustekinumab. Ensure you attend routine cancer screening when invited, for example, cervical screening for women (previously known as the smear test).

IS IT SAFE TO TAKE OTHER MEDICINES ALONG WITH USTEKINUMAB?

Tell your doctor or pharmacist if you are taking, have recently taken or might start taking any new medicines. This includes any complementary and alternative medicines. Most other drugs can be taken safely whilst on ustekinumab, but it's always best to check first. In particular, you should let your doctor or pharmacist know if you currently or have recently been taking any other drugs that weaken the immune system.

IS USTEKINUMAB USED IN COMBINATION WITH OTHER DRUG TREATMENTS FOR IBD?

Your doctors will advise you on this as they plan your treatment. Immunomodulators such as azathioprine, methotrexate or mercaptopurine (6-MP) and steroids can be taken during treatment with ustekinumab. See our information sheet on **Taking Medicines** for more information on taking more than one medicine, which is known as combination therapy.

CAN I HAVE VACCINATIONS WHILE TAKING USTEKINUMAB?

It is unsafe to have live vaccines while on ustekinumab and for 15 weeks after you stop treatment. You should avoid live vaccines, including BCG (tuberculosis), MMR (measles, mumps and rubella), Varicella-Zoster (chicken pox/shingles), yellow fever and the oral typhoid vaccine.

The annual flu jab is recommended and is safe as it is not a live vaccine, however the nasal spray used for the children's flu vaccine is live and should not be used if you are taking ustekinumab. See our information sheet **Travel and IBD** for more information on live vaccines.

CAN I DRINK ALCOHOL WHILE TAKING USTEKINUMAB?

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

DOES USTEKINUMAB AFFECT FERTILITY OR PREGNANCY?

The effects of ustekinumab on fertility are not yet known. Although ustekinumab did not appear to affect fertility in animal studies, the effect on human fertility has not been studied.

Taking ustekinumab while pregnant is not recommended as the effects of ustekinumab during pregnancy and on the unborn baby are unknown. If you are a woman who could get pregnant, you should use effective contraception while taking ustekinumab, and keep using it for at least 15 weeks after your last dose. If you are planning a pregnancy, please discuss this with your IBD team first, and if your pregnancy is unplanned, notify your IBD team as soon as possible.

WHAT ABOUT AFTER BREASTFEEDING?

Ustekinumab has been found to pass into breast milk in low levels in animal studies, but it is unknown whether it does the same in humans, or if it may be harmful to the baby. Women should speak to their doctor if they are breastfeeding or planning to breastfeed, as breastfeeding should be avoided when taking ustekinumab.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about side effects, or have other questions about your ustekinumab treatment, discuss them with your specialist doctor or IBD nurse. They should be able to help you with queries such as why it has been prescribed, what the correct dose and frequency is, what monitoring is in place, what you should do if new symptoms occur, and what alternatives are available.

HELP AND SUPPORT FROM CROHN'S & COLITIS UK

We're here for you whenever you need us. Our award-winning publications 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, school and employment. We'll help you find answers, access support and take control.

All publications are available to download from our website:
crohnsandcolitis.org.uk/publications

Health professionals can order some publications in bulk by using our online ordering system, available from the webpage above.

If you would like a printed copy of a booklet or information sheet, please contact our helpline.

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 to live well with your condition
- help you understand and access disability benefits
- be there to listen if you need someone to talk to
- put you in touch with a trained support volunteer who has a personal experience of Crohn's or Colitis.

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

See our website for Live Chat: **www.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 and about

If you become a member of Crohn's & Colitis UK, you will get benefits including a

Can't Wait Card and a RADAR key to unlock disabled toilets. 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.

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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 and 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 www.crohnsandcolitis.org.uk