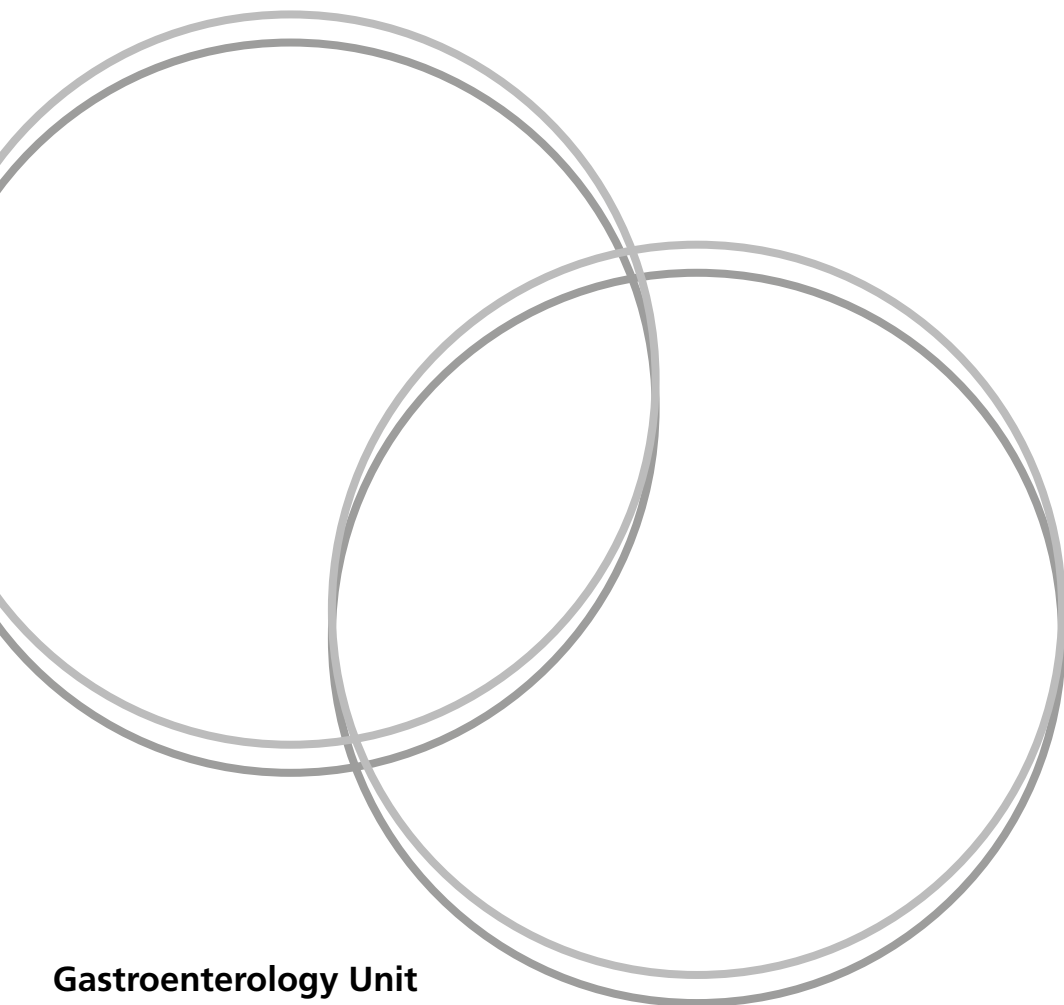




Oxford University Hospitals
NHS Foundation Trust

USTEKINUMAB (Stelara®)

Information for patients



Gastroenterology Unit

This leaflet answers some of the common questions asked about ustekinumab (Stelara).

Further information can be found in the information leaflet supplied by the manufacturer (inside the box) or from your pharmacist, IBD nurse specialist or doctor.

Why am I having ustekinumab?

Ustekinumab is licensed to treat people with Crohn's disease and ulcerative colitis which have not responded well to corticosteroid treatment (such as prednisolone or budesonide), immunomodulators (azathioprine, mercaptopurine, and/or methotrexate) and/or other biological therapy (such as infliximab or adalimumab (anti-TNF agents)). In addition, it can be used if you are not able to take these treatments.

Ustekinumab is also licensed to treat certain types of psoriasis and psoriatic arthritis.

How does ustekinumab work?

Ustekinumab works differently to other medications used to treat Crohn's disease and ulcerative colitis. It targets and blocks the action of two proteins (cytokines) in the body, called IL-12 and IL-23. These are involved in causing inflammation in the bowel, which is associated with Crohn's disease. This inflammation, if not treated, leads to digestive tract damage, which causes symptoms including pain, diarrhoea and bowel cramping.

What dose should I be taking?

You will receive the first dose of ustekinumab in hospital. It will be given to you as an intravenous infusion (liquid) into a vein in your arm.

You will have the second dose 8 weeks later, as an injection under the skin (subcutaneous injection). A nurse will show you how to give yourself this injection, so you can self-administer future doses at home.

These first two doses are called the induction doses. If you respond well to these doses you can continue treatment. The standard maintenance treatment is 90mg (one pre-filled syringe) as a subcutaneous injection, every 8 weeks. Your personal dosing schedule will be explained to you.

Please contact your pharmacist, IBD nurse specialist or doctor if you have any questions about when to take your dose.

How long will it take to work?

You will be reviewed around 16 weeks after starting treatment (after the initial infusion and one injection). We will check whether the treatment is working and if you are experiencing any side effects.

From the research data available, up to 6 out of 10 people (60%) will show some response to treatment in the first 16 weeks. If there is no benefit after 16 weeks then treatment will be reviewed.

Where do I get further supplies of ustekinumab?

Ustekinumab is a specialist medicine which can only be prescribed by the hospital and not your GP. After the intravenous dose you receive in hospital, further doses are administered as a subcutaneous (under the skin) injection and will be prescribed by the hospital and delivered directly to your home or other nominated address, using a homecare delivery service. Nurse training will be provided for the self-administration of the injection as required.

A gastroenterology pharmacist will discuss the supply process with you.

How should ustekinumab be stored?

Ustekinumab should be stored in the fridge until you need to inject it, ideally between 2-8°C. It should be kept in its original package, to protect it from light.

Current information allows one syringe to be OK to administer if kept at room temperature for a maximum of 28 days. or by the original expiry date , whichever is earlier. Once a syringe has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator.

If you need to travel with your injections, we advise buying a cool bag with a separate pouch inside for ice packs (if a separate pouch is not available, put a barrier between the ice packs and the medication to stop it from freezing). Make sure there is a fridge at your destination to store the medication in and put the injections in there as soon as you can when you arrive.

We can advise you on travelling by aeroplane with injections, as it is likely you will need a letter to explain why you have to take them with you.

How long will I have the ustekinumab treatment for?

If you continue to show a good response to treatment, you will be asked to continue your injection every 8 weeks. If you start to lose response to treatment, we will review the dose frequency (interval between doses) or consider switching you to a different medication.

Do not increase the dose unless your medical team at the hospital have told you to.

When you start the injections we will review you at least once a year to confirm you are still responding to treatment. It is very important for you to come to these appointments, so we can monitor your treatment appropriately. If you repeatedly miss your appointments we will consider stopping your treatment.

What should I do if I miss a dose of ustekinumab?

If you miss or have had to delay your dose of ustekinumab, contact the IBD team so they can advise when you should take the next dose and update their records.

What side effects could I experience?

Please also refer to the information leaflet provided by the manufacturer.

In general, ustekinumab doesn't tend to cause any serious side effects. Most side effects are mild. However, like other medicines that affect your immune system, serious side effects can occur.

The most common side effects reported (in more than 1 in 10 people) includes pain and discomfort where the injection has been given, infections of the nose or throat (runny/blocked nose, sinus infection), dizziness, headache, itching, nausea, vomiting and diarrhoea.

Less common side effects (occurring in up to 1 in 10 people) include more serious infections, a blocked nose and chest infection, skin reactions (hot, red or painful skin, blisters on the skin) and allergic reactions, including a rash.

Ustekinumab has, on rare occasions, been associated with the development of certain serious infections, such as tuberculosis. This is because of the way ustekinumab affects the immune system. We will check that you do not have tuberculosis or other infections before you start treatment with ustekinumab. If you have been previously exposed to tuberculosis or other infections at any time, please let us know before starting the treatment.

On rare occasions, ustekinumab has also been reported to contribute to the occurrence of skin cancers and other cancers, due to its effect on the immune system. Please let us know if you have any form of cancer before starting treatment and/or if you receive a cancer diagnosis once treatment has begun.

It is important that you come for regular follow-up appointments, so we can monitor your blood tests while you are on treatment. We will use these to assess how well your treatment is working.

You should **not self-administer ustekinumab if you experience the following side effects. If you develop one or more of these side effects, please contact the IBD advice line at the hospital:**

- allergic reaction (e.g. chest tightness, wheezing, dizziness, swelling or rash, shortness of breath)
- signs of infection, such as a fever (feeling very hot or cold), stinging when passing urine, feeling tired, productive cough or coughing up green/yellow sputum, feeling sick, toothache/dental problems, or if you have an open cut or wound
- a severe skin reaction, with red and scaly skin that starts in patches and then spreads (exfoliative dermatitis) or psoriasis
- tingling sensation or numbness in any part of your body
- bruising or bleeding very easily or looking very pale.

Please let the gastroenterology team know if you come into close contact with someone who has tuberculosis, either before or after starting your treatment with ustekinumab.

Does ustekinumab interfere with other medicines?

You should tell your doctor all the medicines you are currently taking, even those that are not prescribed (such as over the counter medicines or herbal remedies).

You should not receive live vaccines (e.g. polio or yellow fever) while taking ustekinumab. All 'non-live' vaccines are safe to have whilst taking ustekinumab.

It is recommended that you have the seasonal vaccination against influenza, pneumococcal polysaccharide vaccine (to protect against certain types of pneumonia) and COVID vaccination/booster, unless you have been told not to.

Is ustekinumab safe in pregnancy or if I am breastfeeding?

Ustekinumab is a new medication, so there is limited information on its safety for women who are pregnant or breastfeeding.

If you are planning a pregnancy or become pregnant whilst taking ustekinumab, you must let your specialist know. They will discuss the benefits and risks of continuing or stopping your treatment during your pregnancy. You should avoid breastfeeding whilst taking ustekinumab, as there is not enough information about whether it is safe to do so.

How to contact us

If you need advice about your treatment with ustekinumab, please telephone the IBD advice line.

Tel: **01865 228 772**

There is an answerphone service available 24 hours a day. The team will aim to reply within 24 hours on working days (Monday to Friday).

Email: **ibd.advice@nhs.net**

If you need to arrange further supplies of ustekinumab through the hospital Pharmacy, please contact the Gastroenterology Pharmacist:

Tel: **01865 221 523**

(9.00am to 5.00pm, Monday to Friday)

Email: **ibd.homecare@nhs.net**

They will aim to respond to you within 1 working day.

Keep all medicines out of the reach of children.

Never give any medication prescribed for you to anyone else.

It may harm them, even if their symptoms are the same as yours.

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

Authors: Lloyd Thomas and Sarah Cripps, Gastroenterology Pharmacists
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Oxford University Hospitals NHS Foundation Trust
www.ouh.nhs.uk/information



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charity@ouh.nhs.uk | 01865 743 444 | hospitalcharity.co.uk

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