

Ustekinumab for IBD

Points to remember

- Ustekinumab is a safe and effective medicine to treat inflammatory bowel disease (IBD).
- Always attend your scheduled clinic appointments to ensure that you have an approved prescription available when you need to get your next supply of ustekinumab.

What is ustekinumab and how does it work?

Ustekinumab is a complex biological drug known as a 'monoclonal antibody'. Monoclonal antibodies can target very specific parts of your immune system to help control inflammation. Ustekinumab targets a molecule called interleukin (IL); specifically IL-12 and IL-23. Your body naturally produces interleukins as part of its immune response. Overactivity of IL-12 and IL-23 is thought to be what causes ongoing inflammation when you have IBD (Crohn's disease or ulcerative colitis). By blocking their function, ustekinumab reduces this inflammation and the symptoms of IBD.

Why have I been prescribed ustekinumab?

Ustekinumab is used to treat moderate to severe Crohn's disease and ulcerative colitis. It is prescribed if other IBD medicines have not worked or are not suitable for you.

How do I get ustekinumab?

Ustekinumab is an expensive medicine, so there are strict government restrictions and regulations to make it available at a subsidised (lower) price on the PBS. To ensure you can keep using ustekinumab, you will need to have your IBD assessed every 6 months. This may include regular blood tests and an appointment with your IBD team.

Do I need any tests before I start using ustekinumab?

Pre-treatment screening is essential to check that treatment with ustekinumab is suitable for you. This screening may include blood tests and a chest x-ray to check your risk of infection. You may be advised to have one or more vaccinations before you start using ustekinumab. Please see the [IBD – Vaccinations information sheet](#) for more information.

How do I take ustekinumab?

Intravenous (IV) ustekinumab

The first ('loading') dose of ustekinumab is given as an IV infusion, which you can receive in a day infusion centre or in your home. The infusion takes about 60 minutes.

Subcutaneous ustekinumab

After the first IV dose of ustekinumab, your next dose is given as an injection under the skin ('subcutaneously') 8 weeks later, and then every 8 weeks after that. You will be given training on how to handle, inject and dispose of the syringe. Additional resources, such as video tutorials, may also be available to guide you.

Your IBD team will monitor your body's response to this medicine. You may need more frequent ustekinumab doses, depending on your disease and response to the treatment.

How long will I need to use ustekinumab?

If your IBD gets better when you are using ustekinumab, it may be used for the long term. Ustekinumab may lose its effectiveness over time in some people.

Will I have to take other medicines as well as ustekinumab?

Your IBD team will tell you which medicines you will need to start taking, keep taking or stop taking. Your IBD team may advise combining ustekinumab with another medicine, such as azathioprine, mercaptopurine or methotrexate.

Fertility, pregnancy and breastfeeding

Ustekinumab does not affect fertility. It is important that your IBD is controlled by effective medicine before you become pregnant. Tell your doctor if you are thinking of becoming pregnant or find out that you are pregnant.

Although there is limited information, ustekinumab is generally considered safe to use during pregnancy. Most IBD doctors will recommend that you keep using ustekinumab while pregnant, as there may be a greater risk to the baby if you become unwell from stopping treatment. Timing of the doses may be changed during pregnancy, so it's important to plan ahead by talking with your IBD team. Ustekinumab is considered safe to use while breastfeeding.

Mothers using ustekinumab should talk to their IBD team about vaccination of their baby, as the medicines the mother takes during pregnancy can influence the safety of 'live' vaccines after birth. The main vaccine affected in Australia is the rotavirus vaccine. You can ask your IBD team for a medical exemption letter for a vaccine that your child can't safely be given.

What are the possible side effects of ustekinumab?

Ustekinumab is a safe medicine with minimal side effects. Some side effects may happen at the time ustekinumab is given, while others may not appear until some time later.

Although it is uncommon to have a reaction while receiving your ustekinumab loading dose, you will be monitored for infusion-related reactions. These may include a fast heartbeat, light-headedness, nausea (feeling sick), rashes and shortness of breath.

When using the subcutaneous injections, reactions can appear as a patch of raised, red, itchy skin at the place where the dose was injected. Taking an antihistamine can reduce the symptoms of these injection site reactions.

You may also have mild to moderate symptoms in the days to weeks after receiving ustekinumab, including headaches, joint aches, tiredness and a runny nose or sore throat. In many cases, the symptoms will go away, but in some cases they may be serious and need treatment. If the symptoms are severe or continue or bother you, please let your IBD team know.

Immediate reactions to ustekinumab are rare but include fever, rash, hives, facial swelling, headache, chest tightness, shortness of breath and joint pains. If you have a reaction to ustekinumab, tell your doctor or IBD team as soon as possible.

Ustekinumab can increase your risk of infection, although this is uncommon. This may include serious infections, such as tuberculosis, pneumonia and chicken pox. You will be screened for this risk and vaccinated if possible.

Very rare side effects have been seen in a few people. These include worsening of heart problems, encephalopathy (abnormality in the brain) and lung inflammation. The risk of these is very small and needs to be balanced against the benefits of using the medicine. Talk to your doctor about the risks and benefits for you, so that you can make decisions based on your own health and circumstances.

What can I do to keep myself healthy while using ustekinumab?

- Avoid close contact with people who have transmissible infections. Tell your doctor if you have come into contact with anyone who has an infectious condition, such as chicken pox, shingles, whooping cough or measles.
- You should have the flu vaccine every year and the COVID-19, pneumonia and human papillomavirus (HPV) vaccines according to the recommended schedule. You should not have any live vaccines while using ustekinumab and for some time after stopping it. Please see the [IBD – Vaccinations information sheet](#) for more information.

- Women should have regular cervical screening tests, as recommended by your GP.
- You should use a strong sunscreen and protect your skin when outside. Annual skin checks are recommended.
- Always check with your IBD team before starting to take any new medicines, to avoid unwanted interactions with ustekinumab.

Contact your IBD team or GP if you have an infection or persistent fever.

This information leaflet has been designed to give you some important information about ustekinumab. This information is general and not intended to replace specific advice from your doctor or any other health professional. For more information, please talk to your pharmacist, doctor or IBD nurse.

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