

# Ustekinumab for IBD

## Points to remember

- Ustekinumab is a safe and effective medication to treat inflammatory bowel disease (IBD).
- Always attend your scheduled clinic appointments to ensure that you have access to an approved prescription in time for your next ustekinumab dose.

## 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) (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 responsible for ongoing inflammation in IBD. By blocking their function, ustekinumab reduces inflammation and improves symptoms of ulcerative colitis and Crohn's disease.

## Why have I been prescribed ustekinumab?

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

## How do I take ustekinumab?

### Intravenous (IV) ustekinumab:

The first dose of ustekinumab is given as an IV infusion which you can receive in a day infusion centre or in your home. The infusion will take approximately 60 minutes to complete.

### Subcutaneous ustekinumab:

Following the first IV infusion of ustekinumab, your next dose is administered as an injection under the skin

(subcutaneous) 8 weeks later, and then every 8 to 12 weeks ongoing. You will receive training on how to handle, inject and dispose of the injection. Additional resources such as video tutorials may be available to guide you also.

Your IBD team will monitor your response to this medication. You may need more frequent ustekinumab doses depending on your disease and response to therapy.

## Important information about your access to ustekinumab

Ustekinumab is an expensive medication. Hence, it is subject to strict governmental restrictions and regulations to be subsidised on the PBS. To ensure ongoing supply of ustekinumab, you will be required to undergo assessment of your IBD every 6 months. This may include regular blood tests and an appointment with your IBD team.

## Do I need any tests before I start ustekinumab?

Pre-treatment screening is essential to check your suitability for treatment with ustekinumab. The screening may include blood tests and a chest x-ray to assess infection risk. You may be advised to have one or more vaccines prior to commencing ustekinumab. Please refer to the [Vaccinations and IBD information sheet](#).

## How long will I be on ustekinumab?

If you respond to ustekinumab it may be used for the long term. In some people, ustekinumab may lose its effectiveness over time.

## Will I have to take other medications as well as ustekinumab?

Your IBD team will instruct you on the medications you will need to commence, remain on or cease. Your IBD

team may advise combining ustekinumab with medication such as azathioprine, mercaptopurine or methotrexate.

## Fertility, pregnancy and breastfeeding

Ustekinumab does not affect fertility. It is important your IBD is controlled on effective medication before becoming pregnant. Tell your doctor if you are thinking of becoming pregnant or find you are pregnant.

Ustekinumab is generally considered safe in pregnancy from limited data to date. Most IBD doctors recommend continuing ustekinumab while pregnant as there may be a greater risk to the baby if you become unwell from stopping treatment. Timing of doses may be changed during pregnancy, so it is important to plan ahead by talking with your IBD team. Ustekinumab is considered safe in breastfeeding.

Mothers on ustekinumab should discuss vaccination of their infant with their IBD team, as the medications taken during pregnancy can influence the safety of live vaccinations after birth. The main one affected on the schedule in Australia is rotavirus vaccine. You can ask your IBD team for a medical exemption letter for a vaccine your child cannot receive.

## What are the possible side effects of ustekinumab?

All medications can cause side effects, but not everyone experiences them. You will be monitored for side effects by your IBD team.

Some side effects may occur at the time of ustekinumab administration and others may not appear until sometime later.

Although it is not common to have an infusion reaction during your ustekinumab loading dose, you will be monitored for infusion related reactions whilst you receive ustekinumab. These may include fast heartbeat, light-headedness, nausea, rashes and shortness of breath.

When using subcutaneous injections, injection site reactions can manifest as a patch of raised, red, itchy skin where the injection was administered. Antihistamine

treatment can reduce the symptoms of injection site reaction.

You may also experience mild to moderate symptoms in the days to weeks after receiving ustekinumab including headache, joint aches, tiredness and runny nose or sore throat. In many cases, the symptoms will go away, but in some cases they may be serious and require 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 experience a reaction to ustekinumab, notify your doctor or IBD team as soon as possible.

Ustekinumab can uncommonly increase the risk of infection. This may include serious infections such as tuberculosis, pneumonia and chicken pox. You will be screened for this risk and vaccinated where possible.

Rare side effects have been described in a few people. These include worsening of heart problems, encephalopathy (abnormality in the brain) and lung inflammation. These risks are very small and need to be balanced against the benefits of taking the drug. Talk to your doctor about the risks and benefits for you so that decisions can be made based on your individual health and circumstances.

## What can I do to keep myself healthy on ustekinumab?

- Avoid close contact with people with transmissible infections. Tell your doctor if you have come in 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 papilloma virus (HPV) vaccines according to the recommended schedule. You should not have live vaccinations while taking ustekinumab, and for some time after stopping it. Please refer to the [Vaccinations and IBD information sheet](#) for further 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 new medications to avoid unwanted interactions.

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

This information leaflet has been designed to provide you with 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 further information please speak to your pharmacist, doctor or IBD nurse.

## Acknowledgements:

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