

Points to remember

- Adalimumab is a safe and effective medication to treat inflammatory bowel disease (IBD).
- Always attend your scheduled appointments with your IBD team to ensure that you have access to an approved prescription for ongoing adalimumab.

What is adalimumab and how does it work?

Adalimumab is a complex biologic drug known as a monoclonal antibody. Monoclonal antibodies can target very specific parts of your immune system to control inflammation. Adalimumab targets a molecule called tumour necrosis factor-alpha (TNF- α). Your body naturally produces TNF α as part of its immune response. Overproduction of TNF- α is thought to be responsible for ongoing inflammation in IBD. Adalimumab stops the action of TNF- α , reducing the inflammation and allowing the bowel to heal.

Why have I been prescribed adalimumab?

Adalimumab is used to treat moderate to severe Crohn's disease and ulcerative colitis. It is prescribed if other IBD medications have not worked or are not suitable for you. Adalimumab can be used in fistulising Crohn's disease as a first line treatment.

How do I take adalimumab?

Adalimumab is given as a subcutaneous (under the skin) injection. Adalimumab comes in a prefilled syringe or an injection pen. Your IBD nurse will train you how to handle, inject and dispose of adalimumab. Additional resources such as video tutorials may be available to guide you.

Adalimumab for IBD

To start, adalimumab is given as multiple doses closer together and is then given as an injection every 2 weeks ongoing. The number of injections varies by the product, but generally initial and ongoing dosing is as follows:

- Initially 2 to 4 injections (2 x 80mg or 4 x 40mg) on one day.
- Then 1 to 2 injections (1 x 80mg or 2 x 40mg) two weeks later.
- Then 1 injection (40mg) every two weeks ongoing.

There are several versions of adalimumab. All of these have different brand names. Your IBD team will let you know what brand of adalimumab you should be on and remain on unless told otherwise.

Important information about your access to adalimumab

Adalimumab 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 adalimumab, 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 adalimumab?

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

How long will I be on adalimumab?

If you respond to adalimumab it may be used for the long term. In some people, adalimumab can lose its effectiveness over time. Adalimumab blood levels can be checked, and low levels of adalimumab may indicate that the dose has to be increased or be given more often.

Will I have to take other medications as well as adalimumab?

Your IBD team will instruct you on the medications you will need to commence, remain on or cease. There is some evidence that combining adalimumab with medication such as azathioprine, mercaptopurine or methotrexate may be more effective than adalimumab alone.

Fertility, pregnancy and breastfeeding

Adalimumab 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.

Adalimumab is generally considered safe in pregnancy. Most IBD doctors recommend continuing adalimumab 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. Adalimumab is considered safe in breastfeeding.

Mothers on adalimumab 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 adalimumab?

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

Immediate reactions to adalimumab injections are rare but include fever, rash, hives, facial swelling, headache and joint pains. If you experience a reaction to adalimumab, notify your doctor or IBD team as soon as possible. An injection site reaction can manifest as a patch of raised, red, itchy area of skin where the injection was administered. Antihistamine treatment can reduce the symptoms of injection site reaction.

Adalimumab 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 psoriasis-like rashes, a lupus-like condition and worsening of heart problems. Adalimumab may increase your risk of getting some types of cancer, including melanoma and lymphoma (cancer of the lymph glands) and may very rarely cause a condition similar to multiple sclerosis. 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 adalimumab?

- 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 adalimumab, and for some time after stopping it. Please refer to the <u>Vaccinations and IBD</u> <u>information sheet</u> 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 adalimumab. 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:

This resource was developed in 2021 by the GESA IBD Patient Information Materials Working Group that included the following health professionals:

Mayur Garg (Chair, Gastroenterologist)
Aysha Al-Ani (Gastroenterologist)
George Alex (Gastroenterologist - Paediatric)
Vinna An (Colorectal Surgeon)
Jakob Begun (Gastroenterologist)
Maryjane Betlehem (Stomal Therapy Nurse)
Robert Bryant (Gastroenterologist)
Britt Christensen (Gastroenterologist)
Rosemary Clerehan (Educational Linguist)

Susan Connor (Gastroenterologist)
Sam Costello (Gastroenterologist)
Basil D'Souza (Colorectal Surgeon)
Alice Day (Senior Gastrointestinal Dietitian)
Kevin Greene (Consumer Representative)
Geoff Haar (IBD Pharmacist)
Emma Halmos (Senior Gastrointestinal
Dietitian)
Tim Hanrahan (Gastroenterology Trainee)

Katherine Healy (Senior Gastrointestinal Dietitian) Simon Knowles (Specialist Gastrointestinal Psychologist) Taryn Lores (Health Psychologist)

Heidi Harris (IBD Clinical Nurse Consultant)

Taryn Lores (Health Psychologist) Raphael Luber (Gastroenterologist) Antonina Mikocka-Walus (Specialist Gastrointestinal Psychologist) Marion O'Connor (IBD Clinical Nurse Consultant) Meera Rajendran (IBD Pharmacist) Clarissa Rentsch (IBD Pharmacist) Sally Stockbridge (CCA Consumer Representative) Julie Weldon (CCA Consumer Representative)

Charys Winter (IBD Clinical Nurse Consultant)

The development of this resource was led and funded by GESA, independent from pharmaceutical or device companies. It is possible that the above listed contributors have received funding from pharmaceutical or device companies in a different capacity.

Requests and enquiries concerning reproduction and rights should be addressed to: Gastroenterological Society of Australia (GESA) Level 1 517 Flinders Lane Melbourne VIC 3000 | Phone: 1300 766 176 | email: gesa@gesa.org.au | Website: http://www.gesa.org.au

This document has been prepared by the Gastroenterological Society of Australia and every care has been taken in its development. The Gastroenterological Society of Australia and other compilers of this document do not accept any liability for any injury, loss or damage incurred by use of or reliance on the information. This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use, or use within your organisation. Apart from any use as permitted under the Copyright Act 1968, all other rights are reserved. © 2021 Gastroenterological Society of Australia ABN 44 001 171 115.