

Points to remember

- Vedolizumab 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 vedolizumab dose.

What is vedolizumab and how does it work?

Vedolizumab 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. Vedolizumab targets a protein found specifically in the bowel. It blocks migration of inflammatory cells to the area, reducing inflammation in the bowel and improving symptoms of ulcerative colitis and Crohn's disease.

Why have I been prescribed vedolizumab?

Vedolizumab 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 vedolizumab?

Intravenous (IV) vedolizumab:

Vedolizumab can be given as an IV infusion in a day infusion centre, usually at a hospital. The infusion will take approximately 30 minutes to complete. The first three infusions are given close together in a 6-week period and then every 8 weeks ongoing.

Subcutaneous vedolizumab:

Vedolizumab can also be given as a subcutaneous (under the skin) injection. Your IBD team will train you how to handle, inject and dispose of the device. Additional resources such as video tutorials may be available to

Vedolizumab for IBD

guide you. When starting, two to three IV infusions are given close together in a 6-week period and then changed to a subcutaneous injection every 2 weeks ongoing.

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

Important information about your access to vedolizumab

Vedolizumab 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 vedolizumab, 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 vedolizumab?

Pre-treatment screening is essential to check your suitability for treatment with vedolizumab. 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 vedolizumab. Please refer to the Vaccinations and IBD information sheet.

How long will I be on vedolizumab?

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

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

Your IBD team will instruct you on the medications you will need to commence, remain on or cease. Your IBD team may advise combining vedolizumab with

medication such as azathioprine, mercaptopurine or methotrexate.

Fertility, pregnancy and breastfeeding

Vedolizumab 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.

Vedolizumab is generally considered safe in pregnancy from limited data to date. Most IBD doctors recommend continuing vedolizumab 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. Vedolizumab is considered safe in breastfeeding.

Mothers on vedolizumab 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 vedolizumab?

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

Vedolizumab is considered safe and to have a very low rate of side effects.

Some side effects may occur at your infusion and others may not appear until sometime later. Although it is not common to have an infusion reaction, you will be monitored for infusion related reactions whilst you receive vedolizumab. These may include fast heartbeat, light-headedness, nausea, rashes and shortness of breath.

You may also experience mild to moderate symptoms in the days to weeks after the infusion 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.

Vedolizumab can increase the risk of gastroenteritis. Seek medical attention if you develop chills, shivering, persistent cough or a high fever. Other side effects may occur rarely. Talk to your doctor about the risks and benefits for you so that decisions can be made based on your individual health and circumstances

If using subcutaneous injections, injection site reactions 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.

What can I do to keep myself healthy on vedolizumab?

- 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 vedolizumab, and for some time after stopping it. Please refer to the <u>Vaccinations and IBD</u> information sheet for further information.
- Women should have regular cervical screening tests as recommended by your GP.
- 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 vedolizumab. 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.

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