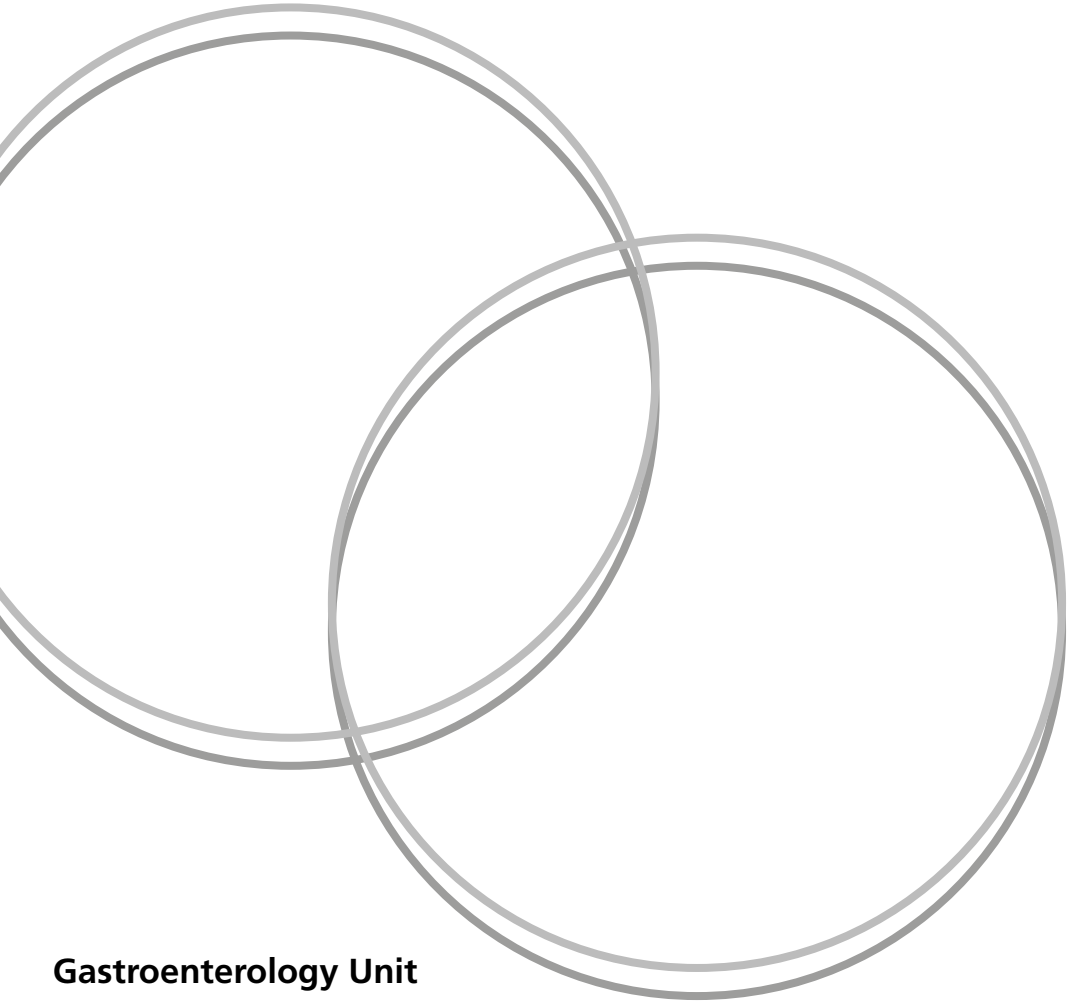
Oxford University Hospitals
NHS Foundation Trust

Vedolizumab (Entyvio®)

Medicines information for patients



Gastroenterology Unit

Vedolizumab (Entyvio®)

This leaflet answers some common questions patients ask about vedolizumab.

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

Why am I having vedolizumab?

Vedolizumab is licensed for patients with moderately or severely active inflammatory bowel disease (ulcerative colitis or Crohn's disease) who have had an inadequate response with, lost response to, or become intolerant to corticosteroids (e.g. prednisolone) and/or an immunomodulator (e.g. azathioprine, mercaptopurine or methotrexate) or a tumour necrosis factor-alpha (TNFα) inhibitor (e.g. infliximab, adalimumab).

How does vedolizumab work?

Vedolizumab interrupts the inflammatory process in the bowel associated with ulcerative colitis and Crohn's disease. It belongs to a group of biological medicines called monoclonal antibodies. Vedolizumab blocks a protein called $\alpha_4\beta^7$ integrin on the surface of white blood cells that cause the inflammation in the gut. It only targets inflammatory cells within the gut. It works differently to other monoclonal antibodies used in the treatment of inflammatory bowel disease like infliximab or adalimumab.

How long does vedolizumab take to work?

Clinical trials have shown that 47% of patients had an improvement in symptoms after 6 weeks with 42% in remission after 1 year. However vedolizumab can take up to 10-14 weeks to show a benefit. If there are no improvements within this time, treatment will be reviewed. For this reason we would not use vedolizumab in an acute, severe flare of inflammatory bowel disease.

What dose will I be given?

Vedolizumab is given as an intravenous infusion at weeks 0, 2 and 6. If you show a response, then you will receive regular maintenance doses every 8 weeks after that as intravenous infusion every 8 weeks in hospital or subcutaneous injection every 2 weeks which you can self-adminster at home.

Intravenous doses are given as a drip infusion. Each infusion will take 30 minutes. Your blood pressure and pulse will be checked during the infusion.

After the first couple of intravenous doses (weeks 0 and 2) we will continue to monitor you for two hours after the infusion has completed. For subsequent doses you will be monitored for one hour after the infusion has completed. The risk of hypersensitivity reactions are more likely following the first two doses.

Please refer to separate information leaflet related to the subcutaneous administration of vedolizumab.

When should I not receive vedolizumab?

You should not be given vedolizumab if you have any previous allergies to the medication or any of its excipients (the inactive substance that serves as the vehicle for the drug) or if you have an active severe infection e.g. tuberculosis, blood poisoning, severe gastroenteritis or an infection affecting the nervous system.

You will have a chest X-ray before receiving vedolizumab. This is to check that you do not have tuberculosis. You must tell your doctor if you have ever had tuberculosis or have been in close contact with someone who has had it.

How long will treatment continue?

If you show a good response you will stay on maintenance treatment. Treatment will initially be for one year and then reassessed.

What are the side effects?

(Please also refer to manufacturer's patient leaflet)

Like all medicines, vedolizumab can cause side effects although not everybody gets them. **You must tell the doctor/nurse immediately if you experience signs of an allergic reaction** e.g.hives, wheezing or difficulty in breathing, itching of the skin, swelling, rapid heartbeat, nausea (feeling sick), pain at the infusion site, redness of the skin, chills or shivering, high fever or rash.

You should also let us know if you experience problems with your sight e.g blurred or loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.

The most common side effects (affecting more than 1 in 10 people) are:

- common cold
- joint pain
- headache.

Other common side effects (affecting up to 1 in 10 people) include fever, chest infection, tiredness, cough, flu, heartburn, back pain, throat pain, sinus infection, itching, rash, throat infection, stomach flu, anal infection, anal sore, hard faeces, bloated stomach, passing gas, high blood pressure, prickling or tingling, haemorrhoids, eczema, muscle cramps, blocked nose, night sweats, muscle cramps/weakness, acne.

Uncommon side effects (affecting up to 1 in 100 people) include:

- redness and tenderness of hair follicles
- oral thrush
- shingles (herpes zoster).

Very rare side effects (affecting up to1 in 10,000 people) include:

- pneumonia
- blurred vision or severe allergic reaction which can lead to breathing difficulty
- swelling
- fast heartbeat
- sweating
- drop in blood pressure
- light-headedness
- loss of consciousness and collapse (also known as an anaphylactic reaction and anaphylactic shock).

Vedolizumab can cause dizziness. **If your experience any dizziness you should not drive or use tools or machinery.**

If you experience any side effects that you are worried about please contact the IBD advice line on the contact number at the end of this leaflet.

Does vedolizumab interfere with my other medicines?

You should inform your Gastroenterologist, IBD nurse specialist or pharmacist of all the medicines you are currently taking, even those not prescribed.

Vedolizumab should not be given with any other biologic treatment that suppresses your immune system e.g.infliximab,adalimumab, golimumab, ustekinumab, tofacitinib, etanercept.

You must inform your Gastroenterologist if you have received natalizumab (a medicine used in multiple sclerosis) or rituximab (a medicine used in cancer or rheumatoid arthritis) in the past before vedolizumab is given.

Live vaccines, in particular live oral vaccines, should be used with caution while on vedolizumab. They should only be used if benefit clearly outweighs the risk and this should be discussed with your Gastroenterologist. Examples of live vaccines include polio and yellow fever. Seasonal vaccination against influenza, and pneumococcal polysaccharide vaccine are recommended.

You should inform your Gastroenterologist or IBD nurse specialist if you are going to receive any vaccination or have recently had a vaccination, as vedolizumab may affect the way you respond to it.

Is vedolizumab ok in pregnancy or breastfeeding?

As vedolizumab is a relatively new treatment there is little information available about its safety in pregnancy. It is expected that some amount of the drug will be transferred across the placenta to the baby, because of the way the drug works, but we do not yet know about its effects.

Until more information is available, plans to have a baby are a factor to be considered before starting vedolizumab. It may be appropriate to consider other treatment options, if they are available. However, it is best to discuss the options and review the most recent information about vedolizumab with your IBD specialist.

If you are on vedolizumab and become pregnant, then careful monitoring and discussion about continuing treatment between yourself, the IBD specialist and obstetric physician would be appropriate.

Vedolizumab is likely to be excreted into breast milk in very small amounts, but currently there is no information to make recommendations about its safety. Information changes rapidly, so it is important to discuss this with the IBD specialist team.

Useful contacts

Gastroenterology Pharmacist
Tel: **01865 221 523**
Email: **ibd.homecare@nhs.net**

IBD advice line
Tel: **01865 228 772**
Email: **ibd.advice@nhs.net**

Online patient information leaflet library:
www.ouh.nhs.uk/patient-guide/leaflets/

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.

Author: Sarah Cripps, Consultant pharmacist – Gastroenterology, June 2015;
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