



INFORMATION SHEET

VEDOLIZUMAB

INTRODUCTION

This information sheet is a brief overview of some of the important points about vedolizumab, which is used to treat Crohn's Disease and Ulcerative Colitis (UC), the two main forms of Inflammatory Bowel Disease - IBD. The information is about vedolizumab in general and is not intended to replace specific advice from your doctor or other health professionals. For further information, please talk to your doctor or specialist IBD team, or look at the information sheet supplied with your medication or from the website: www.medicines.org.uk.

OTHER NAMES FOR THIS MEDICINE

Vedolizumab is a biological drug. You may also hear it called by the brand name Entyvio.

WHY AM I BEING TREATED WITH THIS MEDICINE?

Vedolizumab is used to treat adults over the age of 18 with moderate to severe Crohn's Disease or Ulcerative Colitis.

If you have Ulcerative Colitis, vedolizumab may be an option for you if other treatments such as steroids, 5-ASAs and immunosuppressants have not helped your condition. It also may be an option if you have tried another group of medicines called 'anti-TNF drugs' (such as infliximab or adalimumab) but they did not help your condition.

If you have Crohn's Disease, vedolizumab may be an option if you have tried an anti-TNF and it did not help your condition, or you are not able to take anti-TNF drugs because of your medical history.

In some circumstances, for both Ulcerative Colitis and Crohn's Disease, your doctor may suggest trying vedolizumab before other treatments.

At the moment, there is not enough research about vedolizumab as a treatment for IBD in children, and using it in children is not included in its licence, the document that explains what a medicine will be used for. Even so, if you are under 18 and other treatments have not helped your condition, your IBD team may discuss whether vedolizumab might be an option for you.

HOW DOES IT WORK?

Vedolizumab belongs to a group of medicines called 'biological drugs.' Biological drugs are made from proteins and other substances that occur in nature. They are produced by a biological rather than chemical process – for example they can be created inside living cells.

Vedolizumab is a 'gut-selective integrin blocker' that targets white blood cells. White blood cells are made by the immune system to fight infection. In Crohn's Disease and Ulcerative Colitis, overproduction of these cells leads to inflammation. Vedolizumab works by stopping the white blood cells from entering the lining of the gut. This means that the drug only targets the gut, rather than the whole of the body like anti-TNF drugs, and may cause fewer side effects.

HOW LONG WILL IT TAKE TO WORK?

Everyone responds differently to vedolizumab. Some people may start feeling better within six weeks, but it may take longer. If you have Crohn's Disease, vedolizumab may take up to 14 weeks to work.

HOW DO I TAKE VEDOLIZUMAB?

Vedolizumab is given as an intravenous (IV) infusion – that is, through a drip into a vein in your arm. It cannot be taken orally (in tablet form), because your digestive system would destroy it.

A trained member of staff, normally a nurse or a doctor, will give you infusions of vedolizumab in hospital. You will probably be treated as a day patient, unless you are already in hospital. You will be able to have the infusion while sitting in a chair, so you won't have to undress, get into bed or stay overnight.

Your team will observe you closely during your infusion. For your first two infusions, they will also monitor you for approximately two hours after the infusion has finished. After the first two infusions, you will only need to stay for about an hour after you have completed the infusion.

The infusion itself takes only 30 minutes. It is likely to vary a little, but your whole treatment session may take up to two or three hours in total, including getting ready for the infusion and monitoring afterwards. Treatment time might reduce once you are having regular or maintenance infusions (see below). Check with your IBD team to find out how long you may need to be in hospital.

WHAT IS THE NORMAL DOSAGE AND HOW OFTEN WILL I NEED AN INFUSION?

You will have a 300mg dose of vedolizumab during each infusion.

To begin with, you will have a series of 'starter' infusions during the first six weeks:

- You'll have your first dose,
- then another two weeks later,
- and then another six weeks after the first one.

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If you have Crohn's Disease and you are not improving after your third starter infusion of vedolizumab, your doctor may feel it is valuable for you to have an additional starter dose at week 10.

If you respond well to the treatment, it is likely you will start a maintenance programme of infusions every eight weeks.

If your symptoms do not seem to be improving, your doctor may increase your vedolizumab treatment to infusions every four weeks to see if that helps.

If vedolizumab does not seem to be helping with your symptoms at all, your IBD team may advise stopping treatment:

- after 10 weeks if you have Ulcerative Colitis
- after 14 weeks if you have Crohn's Disease

Sometimes your IBD team may recommend that you try vedolizumab for a bit longer to see if it does start to have an effect.

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It was at least 14 weeks before I could definitively see an improvement. So don't be disheartened if it's not immediate. Vedolizumab is a 'slow burner' but it works for me.

—

Helen, age 37
diagnosed with Crohn's Disease in 2010

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HOW EFFECTIVE IS VEDOLIZUMAB?

Although not everyone responds to vedolizumab, research has shown that vedolizumab can be effective in improving symptoms and bringing about and maintaining remission in people with moderate to severe Crohn's Disease and Ulcerative Colitis. It may also mean you don't have to take steroids.

CAN I HAVE OTHER TREATMENT ALONGSIDE VEDOLIZUMAB?

You might have vedolizumab on its own, or it can be used with other medications to treat IBD, such as anti-inflammatory drugs, steroids or immunosuppressants.

It is important to tell your IBD team if you are taking any medication for other medical conditions, so they can check that they do not interfere with one another.

WHAT CHECKS WILL I NEED BEFORE I START VEDOLIZUMAB?

You will have a check-up before you start your vedolizumab treatment to make sure that it is a suitable treatment for you. The team treating you will ask you if:

- You have an infection, or think you have an infection, or if you've often had infections in the past (this includes fever and flu-like symptoms)
- You are going to have any immunisations or you've had one recently
- You have cancer
- You have a history of liver problems
- You have tuberculosis (TB) or have come into contact with anyone with TB. You should not be given vedolizumab if you have active TB. If you have underlying inactive TB, this will need to be treated before starting vedolizumab. Most doctors now use a blood test to check for underlying or inactive TB, but you may be given a chest x-ray as well
- You are pregnant, planning to get pregnant, or are breastfeeding

Your team will also need to know about any other medications you are taking.

WILL I HAVE ONGOING CHECKS WHILE I AM ON VEDOLIZUMAB?

Your IBD team will monitor you – particularly to check whether vedolizumab is working for you and for signs of infection. You will normally have regular checks and tests to monitor how well the treatment is working. This helps to make sure that any complications are prevented or caught at an early stage. It is also important that you tell your doctor or the hospital team monitoring your treatment about any new symptoms you notice, as soon as they occur.

After 12 months of treatment, your IBD team should give you a check-up to see whether you should continue having vedolizumab. Based on your symptoms they might advise continuing treatment.

Or, if your condition is in complete remission, they may discuss stopping vedolizumab but restarting if you have a relapse or 'flare-up'.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE BEING TREATED WITH VEDOLIZUMAB?

You will need to look out for any of the symptoms listed in the side-effect section. Tell your IBD team if you think you are having an allergic reaction to the infusion, or think you might be getting an infection.

Contact your doctor if you begin to feel unwell and think you may have caught an infection. Your IBD team may recommend that you have an annual flu vaccination, an up-to-date pneumonia vaccination and other vaccinations to prevent you getting infections.

WHAT ARE THE MOST LIKELY SIDE EFFECTS OF VEDOLIZUMAB?

In general, vedolizumab is safe and has low rates of complications. But, like all drugs, vedolizumab can have side effects, although not everyone will experience these.

Some side effects can happen almost immediately, in direct response to the infusion. Others may not appear for several days, weeks or even longer. Some side effects are mild and will go away on their own, or following adjustment of the infusion programme. Others can be more serious and will require treatment.

Side effects of vedolizumab include the following:

Immediate reactions

It is not common, but some symptoms may mean you are having a reaction to the infusion or an allergic reaction to vedolizumab.

Tell your IBD team immediately if you notice any of the following symptoms during or after your infusion, or contact them straight away if you are at home:

- difficulty breathing
- redness of the skin, an itchy rash or itchy skin
- swelling anywhere in your body
- rapid heart rate
- feeling sick
- pain in the part of your arm where the infusion needle was inserted
- chills, shivering, or high fever

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I've had very few side effects from vedolizumab since starting it a month and a half ago, only achy legs and headaches for a day. So far it's been the most effective medication for me.

—
Elaine, age 36
diagnosed with Crohn's Disease in 2015

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Other side effects

It is common for people having vedolizumab to develop a cold, joint pain or headaches. Other common side effects include:

- cold and flu-like symptoms such as fever, tiredness, cough, sore throat and blocked nose
- infection in the chest, throat or sinus
- infection or an anal sore (a sore in or near the back passage)
- pain in the limbs or back, muscle cramps and weakness
- changes to your skin such as itching, rashes, redness, prickling, tingling or developing eczema or acne
- stomach and bowel difficulties such as gastroenteritis (vomiting and diarrhoea), bloating, gas, hard faeces, and haemorrhoids (piles)
- high blood pressure
- heartburn
- night sweats

Less commonly, people may experience redness and tenderness of their hair follicles, or yeast infections in their throat or mouth, and some women may have a vaginal infection.

It is extremely rare and no cases have currently been reported for patients taking vedolizumab, but you should also be aware of the symptoms of a brain condition called progressive multifocal leukoencephalopathy (PML).

Let your IBD team know immediately if you have any of these symptoms:

- blurred, 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

For a complete list of side effects of vedolizumab and for more information, see the Patient Information Leaflet provided with your medication, or visit www.medicines.org.uk.

CAN I HAVE IMMUNISATIONS WHILE ON VEDOLIZUMAB?

You can have some immunisations while on vedolizumab, but it may affect the way that you respond to them. Let your IBD team know if you have any immunisations planned.

CAN I TAKE OTHER MEDICINES ALONG WITH VEDOLIZUMAB?

Tell your IBD team if you are taking, have recently taken or might start taking any other medicines. You shouldn't generally take vedolizumab with other types of biologic drugs that suppress your immune system, although there may be some exceptions.

If you have taken natalizumab (a medicine used to treat multiple sclerosis) or rituximab (a medicine used to treat certain types of cancer and rheumatoid arthritis), tell your IBD team, who will decide if you can be given vedolizumab.

CAN I DRINK ALCOHOL WHILE TAKING VEDOLIZUMAB?

Alcohol is not known to have any interaction with vedolizumab, but for general health reasons it is best to keep within the Department of Health guideline limits.

DOES VEDOLIZUMAB AFFECT PREGNANCY AND FERTILITY?

The effects of vedolizumab during pregnancy are not yet known. Taking vedolizumab while you're pregnant is not currently recommended, unless you and your IBD team have decided that the benefits of taking it strongly outweigh any risks to you and your baby.

If you are a woman who could get pregnant, you should use effective contraception while you're having treatment, and keep using it for at least 5 months after your treatment has finished.

If you are planning a pregnancy, please discuss this with your IBD team first, and if your pregnancy is unplanned, notify your IBD team as soon as possible.

There has not been any research about whether vedolizumab has an effect on male fertility. If you are worried about this, ask your IBD team for advice.

WHAT ABOUT BREASTFEEDING?

It is not yet known whether vedolizumab passes into breast milk, or what effect this could have on your baby. So it is important to tell your IBD team if you are breastfeeding or planning to breastfeed.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about your vedolizumab treatment or if you have any questions, contact your IBD team. They will be able to help you with queries such as why it has been prescribed, what the correct dose and frequency are, what monitoring is in place, and what alternatives may be available for you.

HELP AND SUPPORT FROM CROHN'S AND COLITIS UK

All our information sheets and booklets are available to download from our website: www.crohnsandcolitis.org.uk. If you would like a printed copy, please contact our helpline.

Our helpline is a confidential service providing information and support to anyone affected by Crohn's Disease, Ulcerative Colitis and other forms of Inflammatory Bowel Disease (IBD).

Our team can:

- help you understand more about IBD, diagnosis and treatment options
- provide information to help you to live well with your condition
- help you understand and access disability benefits
- be there to listen if you need someone to talk to
- put you in touch with a trained support volunteer who has a personal experience of IBD

Call us on **0300 222 5700** or email info@crohnsandcolitis.org.uk

See our website for WebChat (Live Online):

www.crohnsandcolitis.org.uk/support/information-service

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We hope that you have found this leaflet helpful and relevant. If you would like more information about the sources of evidence on which it is based, or details of any conflicts of interest, or if you have any comments or suggestions for improvements, please email the Publications Team at publications@crohnsandcolitis.org.uk. You can also write to us at Crohn's and Colitis UK, 45 Grosvenor Road, St Albans, AL1 3AW or contact us through the **Information Line: 0300 222 5700**.

ABOUT CROHN'S & COLITIS UK

We are a **national** charity established in 1979. Our aim is to improve life for anyone affected by Inflammatory Bowel Diseases. We have over 33,000 members and 50 Local Networks throughout the UK. Membership starts from £15 per year with concessionary rates for anyone experiencing financial hardship or on a low income.

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