Vedolizumab Patient Information

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JHH IBD

VEDOLIZUMAB (ve-doe-LIZ-oo-mab)

Patient Information Leaflet

Brand Name: Entyvio®

What is Vedolizumab?

Vedolizumab is a biologic medication belonging to a group of medicines called integrin receptor antagonists. It is a type of protein called a monoclonal antibody that has been designed to recognise and attach to a specific protein (integrin α4β7) found on certain white blood cells that cause inflammation in the gut. By blocking this protein, vedolizumab reduces inflammation in the intestines of people with ulcerative colitis and Crohn's disease.

Unlike some other biologic medicines that affect the immune system throughout the entire body, vedolizumab works primarily in the gut. This "gut-selective" action may result in fewer systemic side effects.

What is Vedolizumab used for?

Vedolizumab is approved in Australia for:

- Moderate to severe ulcerative colitis in adults
- Moderate to severe Crohn's disease in adults

It is typically prescribed when other treatments such as corticosteroids, immunomodulators, or other biologics have not been effective, have stopped working, or have caused significant side effects.

How is Vedolizumab given?

Vedolizumab is administered through an intravenous (IV) infusion, which means it is given directly into a vein. The infusion is provided at a hospital or specialised infusion centre and typically takes about 30 minutes. After your infusion, you will need to stay for observation for a short period to monitor for any immediate reactions.

Standard dosing schedule:

- **Initial treatment phase:** Infusions at weeks 0, 2, and 6
- **Maintenance phase:** Infusions every 8 weeks thereafter

Your doctor may adjust this schedule based on your response to treatment. Each infusion contains 300mg of vedolizumab.

Vedolizumab is also available as a subcutaneous (under the skin) injection for maintenance therapy after at least two intravenous infusions. The subcutaneous form is a 108mg pre-filled pen or syringe that you can administer yourself at home every 2 weeks after proper training.

How long does Vedolizumab take to work?

The time to experience benefits from vedolizumab varies between individuals:

- Some patients notice improvement in symptoms within 3-4 weeks
- Many patients require 6-8 weeks before noticing significant improvement
- Full effectiveness is typically assessed after 10-14 weeks (after the third infusion)

If you don't experience improvement after 14 weeks (following your third infusion), your doctor may consider adjusting your treatment plan.

Instructions for administration (subcutaneous injections only)

If you are using the subcutaneous formulation:

Preparing for injection:

1. Remove the pre-filled pen/syringe from the refrigerator 30 minutes before injection to allow it to reach room temperature
2. Do not warm vedolizumab in any other way (e.g., do not warm in a microwave or hot water)
3. Check the expiration date and appearance of the solution (it should be clear to opalescent, colourless to light brownish-yellow)
4. Do not use if the solution is cloudy, discoloured, or contains particles
5. Wash your hands thoroughly with soap and water
6. Choose an injection site (abdomen, thighs, or upper arms) and clean with an alcohol swab
7. Wait for the skin to dry before injecting

After injection:

1. Do not rub the injection site
2. If there is bleeding, press a cotton ball or gauze gently on the site for a few seconds
3. Dispose of the used pen/syringe in a sharps container
4. Record the date, site of injection, and any side effects in a diary

How should Vedolizumab be stored?

Intravenous infusion:

As this is administered at a healthcare facility, you will not need to store the medication yourself. The healthcare facility will store vedolizumab in refrigerated conditions (2-8°C) as required.

Subcutaneous injection (if prescribed):

- Store in a refrigerator at 2°C to 8°C (36°F to 46°F)
- Do not freeze
- Keep the pre-filled pen or syringe in the original carton to protect from light
- If needed, the pen or syringe can be kept at room temperature (up to 25°C/77°F) for up to 7 days
- Once stored at room temperature, do not return to the refrigerator
- Keep out of reach of children

What monitoring is required while taking Vedolizumab?

Before starting vedolizumab:

- General blood tests to check blood counts and liver function
- Testing for tuberculosis may be recommended, although less commonly required than with TNF inhibitors
- Stool tests to rule out certain infections

During treatment:

- Regular monitoring of symptoms and disease activity
- Occasional blood tests to monitor:
  - Full blood count
  - Liver function
  - Kidney function
- Less intensive monitoring is generally required compared to other biologic therapies due to vedolizumab's gut-selective action

What are the common side effects of Vedolizumab?

Common side effects (affecting more than 1 in 10 people):

- Nasopharyngitis (common cold)
- Headache
- Joint pain
- Nausea

Less common side effects (affecting between 1 in 100 and 1 in 10 people):

- Upper respiratory tract infection
- Bronchitis
- Flu-like symptoms
- Sinusitis
- Rash or itching

- Infusion-related reactions
- Back pain
- Muscle pain
- Fatigue
- Fever
- Cough

For the subcutaneous formulation, injection site reactions (redness, pain, swelling) may occur.

What are the risks associated with Vedolizumab?

Serious risks:

1. **Allergic and infusion reactions:**
   - Mild to severe allergic reactions can occur during or shortly after infusion
   - Symptoms may include rash, itching, swelling of lips/tongue, difficulty breathing, wheezing, flushing, dizziness, fever, or chest discomfort
   - Severe reactions are rare but can be serious
2. **Infections:**
   - Vedolizumab may increase your risk of infections, primarily affecting the gastrointestinal tract
   - Upper respiratory tract infections are also common
   - The risk of serious systemic infections is lower than with some other biologics due to vedolizumab's gut-selective action
3. **Liver injury:**
   - Rare cases of liver injury have been reported
   - Your doctor will monitor your liver function with blood tests
4. **Progressive Multifocal Leukoencephalopathy (PML):**
   - PML is a rare but serious brain infection caused by the JC virus
   - No cases of PML have been confirmed in patients receiving vedolizumab alone
   - Symptoms include progressive weakness on one side of the body, clumsiness, vision problems, and changes in thinking, memory, and orientation

Vaccinations and Vedolizumab

Before starting vedolizumab:

It is recommended to update all vaccinations according to the Australian Immunisation Schedule before starting treatment. This includes:

- Influenza vaccine (yearly flu shot)
- Pneumococcal vaccine
- Hepatitis B vaccine (if you are not immune)
- Consider COVID-19 vaccination as per current guidelines
- Consider zoster vaccine (Shingrix) if you are over 50 years old

During vedolizumab treatment:

- The effects of vedolizumab on vaccine efficacy and safety haven't been as extensively studied as with other biologics
- **Live vaccines** should be used with caution and discussed with your doctor first:

- Measles, mumps, rubella (MMR)
- Varicella (chickenpox)
- Zoster (Zostavax)
- Oral typhoid
- Yellow fever
- BCG (tuberculosis)
- Oral polio vaccine

- **Non-live vaccines** are generally considered safe:
  - Influenza vaccine (yearly)
  - Pneumococcal vaccine
  - Tetanus booster
  - COVID-19 vaccines

Always discuss vaccination plans with your gastroenterologist before receiving any vaccine.

Vedolizumab and Pregnancy

Planning pregnancy:

Vedolizumab is classified as Category B1 in the Australian pregnancy categorisation system. This means that it has been taken by only a limited number of pregnant women without an observed increase in malformation or harmful effects on the foetus.

Current evidence suggests that vedolizumab:

- Is considered low risk during pregnancy
- Does not appear to increase the risk of birth defects
- Has limited placental transfer during the first two trimesters
- May help maintain disease remission during pregnancy, which is important for healthy pregnancy outcomes

During pregnancy:

- Vedolizumab crosses the placenta, primarily during the third trimester
- Your doctor may recommend adjusting the timing of your last infusion before delivery to minimise infant exposure
- The decision to continue vedolizumab during pregnancy should be discussed with your gastroenterologist and obstetrician

Breastfeeding:

- Small amounts of vedolizumab may pass into breast milk
- Current evidence suggests that breastfeeding while on vedolizumab is generally safe for the infant
- The benefits of breastfeeding and controlling your disease should be discussed with your healthcare providers

Special Precautions

Surgery:

If you are planning to have surgery, inform your surgeon that you are taking vedolizumab. For major surgery, your doctor may recommend timing the procedure between vedolizumab doses.

Travel:

- Consider carrying a letter from your doctor explaining your need for vedolizumab when travelling
- If travelling with subcutaneous vedolizumab, ensure it remains cold (using a special medication travel cooler)
- If travelling overseas, check if you need additional vaccinations and discuss with your doctor
- Plan your travel around your infusion schedule

Monitoring for infections:

While vedolizumab has a lower risk of serious infections compared to some other biologics, you should still:

- Watch for signs of infection (fever, persistent cough, night sweats, painful urination)
- Practice good hand hygiene
- Avoid close contact with people who have active infections when possible

Where can I find more information?

- Speak to your gastroenterologist, IBD nurse, or pharmacist
- Contact the Gastroenterological Society of Australia (GESA): www.gesa.org.au
- Contact Crohn's & Colitis Australia: www.crohnsandcolitis.com.au or 1800 138 029
- Call Medicines Line: 1300 MEDICINE (1300 633 424)

This information leaflet is not intended to replace medical advice. Always consult your healthcare team with specific questions about your treatment.

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