Vedolizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Monitoring requirements - see below
- **Anaphylaxis** can be a concern with this drug- ensure adrenaline, corticosteroids, antihistamine and paracetamol are available.
- **Before** administration of each dose the patient should be examined for the **presence of infection** and consideration given to delaying treatment should a severe infection be present
- Vedolizumab is **contraindicated in patients with active tuberculosis**. Before starting treatment, patients must be screened for tuberculosis according to the local practice. If latent tuberculosis is diagnosed, appropriate treatment must be started in accordance with local recommendations, before starting vedolizumab.
- **Caution** should be exercised when considering Vedolizumab in patients previously treated with **natalizumab or rituximab** (see SPC for more information).
- The concomitant use of Vedolizumab with **biologic immunosuppressants is not recommended**
- In order to improve the traceability of biological medicinal products, **the name and the batch number of the administered product should be clearly recorded.**

Available preparations

Entyvio 300mg vial

Reconstitution

Water for injections

- **Gloves, protective eyewear and a mask** should be worn by those handling this drug (ref 1)
- Add **4.8ml per 300mg vial**
- Use a syringe with a 21-25 gauge needle
- Direct the stream of Water for Injections to the wall of the vial to avoid excessive foaming
- Gently swirl the vial for at least 15 seconds
- **Do NOT** shake vigorously or invert
- **Allow the solution to stand for up to 20 minutes at room temperature** for any foam to settle. If not fully dissolved after 20 minutes allow another 10 minutes for dissolution
- Check that the solution is clear or opalescent, colourless to light yellow and free of visible particulates
- Requires further dilution before administration

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intermittent intravenous infusion (using an electronically controlled infusion device)

- Prior to withdrawing reconstituted solution from vial, gently invert vial 3 times
- Withdraw 5 ml (300 mg) of the reconstituted solution using a syringe with a 21-25 gauge needle
- Add the 5 ml to **250 ml of sterile 0.9% sodium chloride** solution, and gently mix the infusion bag (5 ml of 0.9% sodium chloride solution does not have to be withdrawn from the infusion bag prior to adding Vedolizumab)
- Administer **over 30 minutes**

Dose in adults

Ulcerative Colitis

- Recommended dose is **300 mg administered at 0, 2 and 6 weeks and then every eight weeks** thereafter.
- Continued therapy should be carefully reconsidered if **no** evidence of therapeutic **benefit** is observed by **Week 10**.
- Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to Vedolizumab 300 mg every four weeks.
- If therapy is interrupted and there is a need to restart treatment with Vedolizumab, dosing at every four weeks may be considered.

Crohn's Disease

- Recommended dose is **300 mg administered at 0, 2 and 6 weeks and then every eight weeks** thereafter.
- Patients who have not shown a response may benefit from a dose of Vedolizumab at Week 10.
- Continue therapy every eight weeks from Week 14 in responding patients.
- Discontinue if no evidence of therapeutic benefit is observed by Week 14.
- Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to 300 mg every four weeks.
- If therapy is interrupted and there is a need to restart treatment, dosing at every four weeks may be considered

Patients with renal or hepatic impairment

- Vedolizumab has not been studied in these patient populations. No dose recommendations can be made

Monitoring

- Observe patients continuously during each infusion
- **For the first two infusions, the patient should also be observed for two hours following completion of the infusion for signs and symptoms of acute hypersensitivity reactions**. For all **subsequent infusions**, patients should be observed **for one hour** following completion of the infusion.
- For infusion related reactions please see Medication Protocol: Management of infusion related patient reactions in the nurse led infusion settings at Galway University Hospitals. Available on Q-Pulse CLN-NM-0118
- Levels may be monitored in GUH - see below

Further information

- It is recommended that all patients are up to date with all immunisations prior to initiating (see SPC for more information on vaccines)

- Due to the potential risk of progressive multifocal leukoencephalopathy (PML) patients should be monitored for any new onset or worsening of neurological symptoms and be given a neurological referral if they occur
- All new patients should receive a patient information leaflet (PIL) and a patient alert cardÂ

Storage

- Store between 2 and 8^{0}C
- Since no preservative is present it is recommended that the infusion be used as soon as possible following reconstitution and dilution

References

SPC 07/03/2024

1: Clinical Oncology Society of Australia. Position statement: safe handling of monoclonal antibodies in healthcare settings update 2022, published March 2023

Therapeutic classification

Monoclonal Antibody