

VEDOLIZUMAB

Vedolizumab (Entyvio, Takeda) is a 100% humanised monoclonal antibody against $\alpha 4\beta 7$ integrin, which is responsible for directing white blood cells to inflamed bowel tissue due to Crohn's disease and ulcerative colitis.

Why Vedolizumab?

Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease only if:

- a tumour necrosis factor alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment)
- a tumour necrosis factor alpha inhibitor cannot be tolerated or is contraindicated.

How do I take it?

It is administered by intravenous infusion over 30 minutes followed by 120 minutes (60 minutes during maintenance treatment) observation.

Vedolizumab 300mg is given at 0, 2 and 6 weeks, then every 8 weeks thereafter. People who have not shown a response may benefit from a dose at week 10. If no evidence of therapeutic benefit is seen by week 14, vedolizumab should not be continued.

What are the side effects?

- Common (5-10%): nasopharyngitis (inflammation of the nose and throat), headache, nausea and arthralgia (joint pain)
- Acute infusion reaction (4%). Usually occurs during first or second infusion
- Liver injury may occur (2%)
- Less than 1% of patients taking vedolizumab had a serious infection.

Contraindications to Treatment

- Patients with TB, severe infections or abscesses
- Previous or current treatment with rituximab, natalizumab or TNF-alpha inhibitors
- Patients who are pregnancy or breast-feeding
- Patients with a history of lymphoma or cancer
- Patients with liver disease

Does it work?

Crohn's disease

GEMINI II trial showed that at 10 weeks, 27% of patients had entered clinical remission with vedolizumab (12% given placebo). In those patients who had failed a TNF alpha inhibitor 22% entered clinical remission (11% given placebo).

By 52 weeks in patients who had failed a TNF alpha inhibitor, responded to induction treatment and received vedolizumab every 8 weeks, 28% remained in clinical remission.

Ulcerative colitis

At the end of induction (week 6), 17% of patients treated with vedolizumab were in clinical remission.

57% people in the 8 weekly vedolizumab arm had a "durable clinical response" (a clinical response at both week 6 and 52) but only 20.5% had a durable clinical remission (remission at both week 6 and 52).

Discontinuation of treatment with vedolizumab due to side effects or lack of effect occurred in 44% of patient during the maintenance phase of the trial.

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