

## Pharmacotherapeutic report Infliximab (Remicade®) for the indication 'colitis ulcerosa'

### Infliximab (Remicade), 100 mg powder for concentrate for solution for infusion

#### Summary

##### Therapeutic value

**Intended effects.** Infliximab promotes disease remission in moderate to severe cases of colitis ulcerosa. The efficacy of ciclosporin is much less well-documented. This means that insufficient information is available to be able to assume that ciclosporin is also more efficacious than placebo or i.v. corticosteroids in the induction of disease remission. It is not clear whether infliximab reduces the risk of colectomy after a year.

**Unintended effects.** During the induction of remission, in comparison with ciclosporin, infliximab is associated with more infusion-related side effects and infections, the most important of which is reversible renal function deterioration.

**Experience.** Ample experience has been obtained with infliximab and ciclosporin. This experience has largely been obtained with other indications than colitis ulcerosa.

**Applicability.** The applicability of infliximab is the same as that of ciclosporin.

Infliximab has more contraindications, ciclosporin more interactions.

**Ease of use.** Infliximab is easier to use than ciclosporin due to the shorter administration time.

**Final conclusion.** For the treatment of moderate to severe cases of colitis ulcerosa, in comparison with ciclosporin, infliximab has a therapeutic added value in achieving disease remission.

##### Comparison between t = 0 and t = 4

When assessing infliximab's provisional inclusion (t = 0), the CFH concluded that the added value of infliximab exceeded that of ciclosporin. Its efficacy was assessed at that time on the basis of 'clinical response' and it has been assessed (t = 4) on the basis of 'clinical remission', both after 8-12 weeks. The prevention of colectomy after 12 months was not assessed at the time and it is now difficult to assess because infliximab is suitable for both inducing remission and preventing exacerbation, while ciclosporin is only suitable for inducing remission. Again based on an indirect comparison, the assessment for continued inclusion in the 'Expensive Medicines' policy regulation indicates that infliximab has a therapeutic added value in comparison with ciclosporin.

Finalized October 24, 2011.

*The original text of the summary of this outcome of assessment was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the summary of the report. Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*