

# Infliximab Biosimilar (Remsima™) in Therapy of Inflammatory Bowel Diseases Patients: Experience from One Tertiary Inflammatory Bowel Diseases Centre

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## Key Words

Biosimilar · Infliximab · Switching · Inflammatory bowel diseases

## Abstract

**Background:** The evidence on the efficacy and safety of biosimilar infliximab (IFX) in patients with inflammatory bowel diseases (IBD) is sparse. **Methods:** Consecutive IBD patients visiting our centre were included. One cohort composed of prospectively followed patients who were switched from original to biosimilar IFX between January and March 2015. The second cohort included retrospectively assessed anti-tumor necrosis factor  $\alpha$ -naïve patients who started therapy between January 2015 and January 2016. Disease activity was assessed using standard clinical indices, endoscopic evaluation, and laboratory parameters (blood count, C-reactive protein (CRP) and fecal calprotectin (FC)). Trough levels and anti-drug antibodies (ATIs) were also measured. Patients were evaluated 56 weeks (W56) after switch and at week 14 (W14) and week 46 (W46) in the naïve cohort. **Results:**

Seventy-four IBD patients were switched to biosimilar IFX and 119 naïve patients newly initiated therapy with the preparation. Disease activity remained stable in a majority of switched patients (remission at week 0 (W0) vs. W56: 72.2 vs. 77.8%; median difference of both Harvey-Bradshaw index and Simple Clinical Colitis Activity Index between W0 and W56 was 0). When W0 and W56 were compared, no significant difference in CRP ( $4.3 \pm 8.0$  vs.  $3.3 \pm 3.8$  mg/l;  $p = 0.89$ ) and FC ( $135 \pm 153$  vs.  $199 \pm 225$   $\mu$ g/g;  $p = 0.17$ ) was observed. In total, 92% of Crohn's disease (CD) and 83% of ulcerative colitis (UC) patients responded to induction therapy (W14) with biosimilar IFX. At W46, the response rate was 86% in CD and 64% in UC. Moreover, half of UC patients experienced mucosal healing at W14 and improvement of perianal disease occurred in 95% of CD at W46. In this cohort, clear steroid-sparing effect was observed. No increase in immunogenicity was found in switched patients (ATI positivity: 9.5 vs. 6.0%,  $p = 0.54$ ) and the type and frequency of adverse events were comparable to the original preparation in both cohorts. **Conclusion:** Switching of IBD patients from original to biosimilar IFX is effective and safe. © 2017 S. Karger AG, Basel