

Randomized, double-blind, double dummy trial. Patients with Mild-Moderate UC were randomized to:

Treatment arms: Budesonide 9 mg (9MMX) vs 6 mg (6MMX) vs 5ASA 2.4gr/day vs placebo.

Primary outcome:

- Combined clinical and endoscopic remission at week 8.

Results:

- Combined remission at week 8: 17.9% (9MMX) vs 13.2% (6MMX) vs 12.1% (5ASA) vs 7.4 (placebo). (p=0.0143; p=0.1393; p=0.22)
- Clinical improvement rates w8: 33.3% (9MMX); 30.6% (6MMX); 33.9% (5ASA); 24.8% placebo; p=ns all comparisons

Conclusions:

Budesonide MMX 9 mg safe and more effective than placebo, 5ASA & MMX 6 mg inducing remission

In 2014 The CORE II trial explored Budesonide MMX 9 mg vs 6 mg vs Entocort 9 mg vs placebo. The findings confirmed that Budesonide MMX 9 mg was superior.

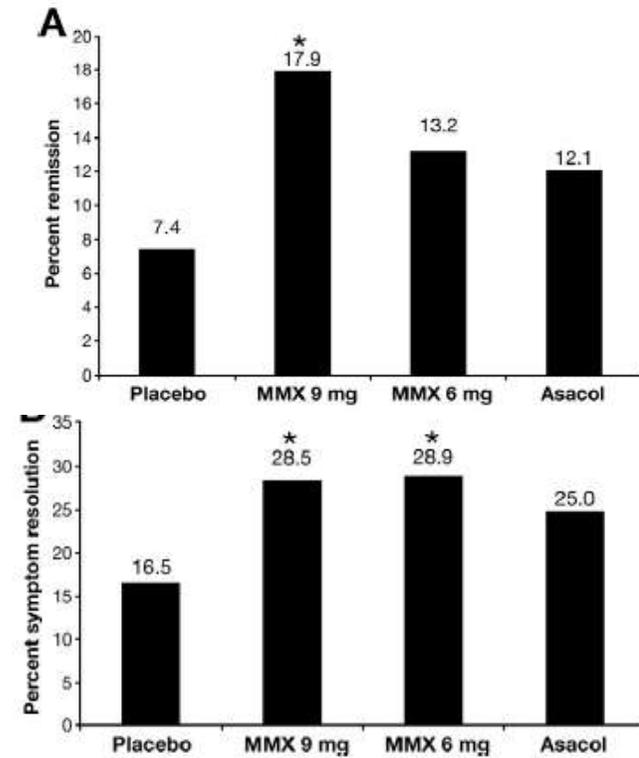


Figure 1. (A) Combined clinical and endoscopic remission at week 8. Modified ITT population, N = 489. *Statically significant ($P < .025$). (B) Symptom resolution at week 8. Modified ITT population, N = 489. *Statically significant ($P < .05$). This study was not powered to show a statistical difference between budesonide MMX treatment arms and Asacol.

