

Clinical trial: ulcerative colitis maintenance treatment with 5-ASA: a 1-year, randomized multicentre study comparing MMX with Asacol

Randomized double-blind, double-dummy, parallel-group, comparator study.

Patients with left side ulcerative colitis were randomly assigned to: 5ASA-MMX (2.4gr/once daily) vs Asacol (1.2gr/twice daily)

Co primary endpoints: Maintenance of clinical remission (UC-DAI ≤ 1) after 12 months of treatment and clinical and endoscopic remission at 12 months

Results: N=331

- Clinical remission at 12 months: 68% 5ASA-MMX vs 65.9% Asacol, p=0.69
- Clinical and endoscopic remission at 12 months: 60.9% 5ASA-MMX vs 71.7% Asacol, p=0.89

Conclusion:

Once daily 5ASA-MMX is similarly effective with a comparable safety profile to Asacol administered twice daily, for the maintenance treatment of ulcerative colitis.

Table 2. Patients in remission following 12 months' treatment (mITT population)

	5-ASA-MMX		Asacol	
	Clinical (n = 156)	Clinical and endoscopic (n = 156)	Clinical (n = 167)	Clinical and endoscopic (n = 167)
Patients in remission following 12 months' treatment (mITT)				
Remission; n (%)	106 (68.0)*	95 (60.9)†	110 (65.9)*	103 (61.7)†
Treatment failures; n (%)	50 (32.0)	61 (39.1)	57 (34.1)	64 (38.3)
Relapse		39 (25.0)		50 (29.9)
Adverse event		3 (1.9)		3 (1.8)
Other‡	8 (5.1)	18 (11.5)	4 (2.4)	9 (5.4)
Patients in remission following 12 months' treatment, including diary card data (mITT)				
Remission; n (%)	97 (62.2)§	87 (55.8)¶	86 (51.5)§	81 (48.5)¶
Treatment failures; n (%)	59 (37.8)	69 (44.2)	81 (48.5)	86 (51.5)
Relapse		48 (30.8)		74 (44.3)
Adverse event		3 (1.9)		3 (1.8)
Other‡	8 (5.1)	18 (11.5)	4 (2.4)	9 (5.4)

Figure 2. Time to relapse (mITT population) 5-ASA: 5-aminosalicylic acid; mITT: modified intent-to-treat.

