

14.2.2 Secondary endpoints

Table 14.3.3.5: Adverse events incidence - Safety Population

	Period 1 N = 15	Period 2 N = 33	Total N = 33
Patients with any AE	15 (100.0 %)	33 (100.0 %)	33 (100.0 %)
Patients who died from any cause	4 (26.7 %)	10 (30.3 %)	10 (30.3 %)
Patients with any AE of toxicity grade III or higher	9 (60.0 %)	27 (81.8 %)	28 (84.8 %)
Patients with severe AEs	0 (0.0 %)	2 (6.1 %)	2 (6.1 %)
Patients with severe AEs of toxicity grade III or higher	0 (0.0 %)	2 (6.1 %)	2 (6.1 %)
Patients with severe AEs treatment-related	0 (0.0 %)	1 (3.0 %)	1 (3.0 %)
Patients with any AE treatment-related	1 (6.7 %)	8 (24.2 %)	8 (24.2 %)
AE: adverse event. N: number of patients.			
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