

Table 1. Summary of adverse events

Safety population	N=2570
Patients with any AEs, n (%)	1425 (55.4)
Most frequently ^a reported AEs, n (%)	
Dizziness/vertigo	452 (17.6)
Behavioral (aggression/anger/irritability)	403 (15.7)
Somnolence	317 (12.3)
Falls/instability/ataxia	120 (4.7)
Fatigue	118 (4.6)
Depressed mood/mood disturbance	102 (4.0)
AEs leading to discontinuation, n (%)	383 (13.9) ^b
Patients with any psychiatric AE, n (%)	568 (22.1)
Patients with psychiatric AEs leading to discontinuation, n (%)	224 (8.7)
Most frequently ^c reported psychiatric AEs leading to discontinuation, n (%)	
Behavioral (aggression/anger/irritability)	150 (5.8)
Depressed mood/mood disturbance	47 (1.8)
^a ≥4% patients; ^b N=2747; ^c ≥1% patients. AE, adverse event.	