

Table 1. Summary of safety and tolerability

Total patients	N=425
Patients with any AE, n (%)	174 (40.9)
Most frequently reported AEs ^a , n (%)	
Behavioral (aggression/anger/irritability)	64 (15.1)
Somnolence	55 (12.9)
Dizziness/vertigo	45 (10.6)
Patients with AEs leading to discontinuation, n (%)	57 (13.4)
Patients with any psychiatric AE, n (%)	82 (19.3)
Patients with psychiatric AEs leading to discontinuation, n (%)	33 (7.8)
Most frequently reported psychiatric AEs leading to discontinuation ^b , n (%)	29 (6.8)
Behavioral (aggression/anger/irritability)	
^a ≥5% patients; ^b ≥1%. AE, adverse event.	