

Table 1. Summary of safety and tolerability

Total patients	N=38
Patients with any AE, n (%)	23 (60.5)
Most frequently reported AEs ^a , n (%)	
Behavioral (aggression/anger/irritability)	10 (26.3)
Dizziness/vertigo	8 (21.1)
Depressed mood/mood disturbance	3 (7.9)
Anxiety	2 (5.3)
Nausea/vomiting/gastrointestinal problems	2 (5.3)
Somnolence	2 (5.3)
Patients with AEs leading to discontinuation, n (%)	2 (11.1) ^b
Patients with any psychiatric AE, n (%)	11 (28.9)
Patients with psychiatric AEs leading to discontinuation, n (%)	1 (2.6) ^c
^a ≥5% patients; ^b N=18; ^c This patient had a behavioral psychiatric AE but it was not possible to determine if it was this AE that led to discontinuation. AE, adverse event.	